

Message

From: Snyderman, Steven [Snyderman.Steven@epa.gov]
Sent: 9/17/2018 4:38:41 PM
To: Mastrota, Nicholas [Mastrota.Nicholas@epa.gov]
CC: Fletcher, Rachel [fletcher.rachel@epa.gov]; Britton, Cathryn [Britton.Cathryn@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Newcamp, Caitlin [Newcamp.Caitlin@epa.gov]; Jones, Ricardo [Jones.Ricardo@epa.gov]; Friedman, Dana [Friedman.Dana@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Eagle, Venus [Eagle.Venus@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Mannix, Marianne [Mannix.Marianne@epa.gov]
Subject: RE: New Tier-2 Incidents

Thank you Nick!

Steven Snyderman, Chemical Review Manager
Risk Management and Implementation Branch I
Pesticide Re-evaluation Division
Office of Pesticide Programs
Environmental Protection Agency
Snyderman.Steven@epa.gov
(703) 347-0249

From: Mastrota, Nicholas
Sent: Monday, September 17, 2018 12:36 PM
To: Snyderman, Steven <Snyderman.Steven@epa.gov>
Cc: Fletcher, Rachel <fletcher.rachel@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Newcamp, Caitlin <Newcamp.Caitlin@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Mannix, Marianne <Mannix.Marianne@epa.gov>
Subject: RE: New Tier-2 Incidents

Steve,

You are interpreting the data in this newest report correctly. There were 125 alleged pet deaths and 226 alleged major pet incidents reported for Seresto collars in the second quarter of 2018.

I did not prepare the earlier IST summary report, but it looks like the data presented on slides 4 and 5 are actually for **three months**, not for seven months as indicated in the slide title. Attached is an IDS aggregate incident report I ran for DA and DB incidents for flumethrin for the period of August 30, 2017 through April 1, 2018. Since flumethrin is only registered for use in Seresto collars, these numbers represent reported cases for Seresto. The 87 deaths match the number of pet deaths (DA) reported in only the first quarterly report (I030491-009). The number of pet deaths per quarter ranged from 63 to 125, with the 125 coming from the latest aggregate report that we just distributed. The total number of alleged pet deaths for this period is **361**. The total number of alleged deaths (DA) plus severe (DB) incidents reported for this period is **1,393**.

In the IST Summary presentation, the numbers of DA+DB and DA incidents that are presented graphically on slides 6 and 7, respectively, appear to be accurate. These graphs shows approximately 200 to 400 DA+DB incidents occurring per quarter, and approximately 50 to 100 DA (deaths) reported per quarter during the past couple of years, with an trend of increasing numbers. The numbers in this latest report are consistent with that trend. The 125 alleged deaths reported in the latest quarter is the highest number we have seen.

Nick

From: Snyderman, Steven
Sent: Monday, September 17, 2018 11:19 AM
To: Mastrota, Nicholas <Mastrota.Nicholas@epa.gov>
Cc: Fletcher, Rachel <fletcher.rachel@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Newcamp, Caitlin <Newcamp.Caitlin@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>
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The IST reported only 87 pet deaths associated with Seresto specifically within a seven month period (August 30th, 2017 – April 1st, 2018) according to IST's May 9th, 2018 PowerPoint, please correct me if I'm wrong, so I want to confirm I'm reading that information correctly.

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From: Friedman, Dana
Sent: Thursday, September 13, 2018 4:34 PM
To: Snyderman, Steven <Snyderman.Steven@epa.gov>
Subject: FW: New Tier-2 Incidents

FYI

From: Mastrota, Nicholas
Sent: Thursday, September 13, 2018 4:30 PM
To: Fletcher, Rachel <fletcher.rachel@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Newcamp, Caitlin <Newcamp.Caitlin@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>
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Risk managers,

Attached is a package of new aggregated incidents related to Seresto collars. The incidents were labeled a Tier 2 incidents by the OPP Incident Screening Team (IST). Tier 2 indicates that the incidents are not high-priority and generally do not require immediate action, but are significant enough to warrant notification of risk managers, primarily as an FYI. Tier 2 incidents can be addressed in the next registration/registration review action. Please let us know if you have any questions or comments.

Nicholas Mastrota
OPP Incident Screening Team

Message

From: Mastrota, Nicholas [Mastrota.Nicholas@epa.gov]
Sent: 9/17/2018 4:36:02 PM
To: Snyderman, Steven [Snyderman.Steven@epa.gov]
CC: Fletcher, Rachel [fletcher.rachel@epa.gov]; Britton, Cathryn [Britton.Cathryn@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Newcamp, Caitlin [Newcamp.Caitlin@epa.gov]; Jones, Ricardo [Jones.Ricardo@epa.gov]; Friedman, Dana [Friedman.Dana@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Eagle, Venus [Eagle.Venus@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Mannix, Marianne [Mannix.Marianne@epa.gov]
Subject: RE: New Tier-2 Incidents
Attachments: Aggregate Incident Summary Report for Flumethrin.pdf; IST Report Q1 2018 5.9.18.pptx

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Nicholas Mastrota
OPP Incident Screening Team

Message

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 3/3/2021 1:29:26 PM
To: Jennings, Susan [Jennings.Susan@epa.gov]
CC: Siedschlag, Gregory [Siedschlag.Gregory@epa.gov]; Saunders, Jennifer [Saunders.Jennifer@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Overbey, Dian [Overbey.Dian@epa.gov]; Berckes, Nicole [Berckes.Nicole@epa.gov]; Rust, Mary [Rust.Mary@epa.gov]
Subject: Re: TPs for Seresto
Attachments: Seresto_talkingpoints_3-2-2021_revised.docx; DRAFT Seresto press response 2021-03-02.docx

Internal, draft

Thank you, Susan. We are fielding multiple inquiries on this topic, so I am looping in Dian Overby, Nicole Berckes (although she may have already started her detail), and Mary Rust for awareness. I am also attaching a draft press response that we were working on yesterday that may have helpful info for other responses.

Best,
Catherine
Associate Director
OPP Registration Division
US Environmental Protection Agency

On Mar 3, 2021, at 7:51 AM, Jennings, Susan <Jennings.Susan@epa.gov> wrote:

Greg and Jenn,

Attached are talking points that CDC has developed for discussion about their program's use of Seresto collars (as a response to yesterday's article in USA Today). Could you please review these and return any comments? I have reviewed and have no comments and would like to get these back to them as soon as possible.

As background, CDC has an ongoing program (10 years) to control brown dog ticks on tribal lands in AZ and NM because there have been repeated cases of Rocky Mountain Spotted Fever transmitted by dog ticks. Dog ticks have not been known to typically transmit RMSF in other areas, but pest pressure, population habits, weather, and other factors lead to high populations of these ticks in areas inhabited by people. There are also cases of RMSF transmitted by brown dog ticks in northern Mexico. Seresto collars are a critical component of this IPM control program, so CDC is worried about implications from yesterday's article.

Thanks for your help,

Susan.

From: Partridge, Sue (CDC/DDID/NCEZID/DVBD) <snm3@cdc.gov>
Sent: Tuesday, March 2, 2021 5:30 PM
To: Jennings, Susan <Jennings.Susan@epa.gov>
Subject: TPs for Seresto

Hi Susan,

See attached. Comments and edits welcome.

Thanks,
Sue

<Seresto_talkingpoints_3-2-2021_revised.docx>

Message

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]
Sent: 3/2/2021 4:45:03 PM
To: Laws, Meredith [Laws.Meredith@epa.gov]
Subject: FW: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Ex. 5 Deliberative Process (DP)

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Tuesday, March 2, 2021 11:12 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>
Subject: FW: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

FYI

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
571-309-5497 (cell)

From: Dennis, Allison <Dennis.Allison@epa.gov>
Sent: Tuesday, March 02, 2021 10:53 AM
To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>
Subject: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Head's up on this story. We're working up a statement regarding our incident data to use if needed. -Allison

https://apple.news/A78_uo4GiQWq_FP9GTVxg9w

Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Johnathan Hettinger

Midwest Center for Investigative Reporting

Rhonda Bomwell had never used a flea and tick collar before. Pierre, her 9-year-old Papillon service dog, was mostly an indoor animal.

Still, her veterinarian recommended she purchase one, so Bomwell went to the pet store near her home in Somerset, New Jersey, and selected Bayer's Seresto collar.

A day later, on June 2, 2020, Pierre had a seizure, collapsing while Bomwell was making dinner. Lying on his back, the dog stopped breathing and his eyes rolled back.

Bomwell tried giving him CPR. Then she called the police. An officer helped her lift the dog into her car, and she rushed him to the hospital. Pierre died before he could receive medical treatment. Bomwell didn't think to take off Pierre's collar.

"I just didn't put it together," she said.

Bomwell isn't alone. Seresto, one of the most popular flea and tick collars in the country, has been linked to hundreds of pet deaths, tens of thousands of injured animals and hundreds of harmed humans, U.S. Environmental Protection Agency documents show.

Yet the EPA has done nothing to inform the public of the risks.

Seresto, developed by Bayer and now sold by Elanco, works by releasing small amounts of pesticide onto the animal for months at a time. The pesticide is supposed to kill fleas, ticks and other pests but be safe for cats and dogs.



But thousands of pets are being harmed, according to federal documents obtained through a public records request from the Center for Biological Diversity, a nonprofit organization that watchdogs the EPA as part of its work to protect endangered species. The center provided the documents to the Midwest Center for Investigative Reporting.

Since Seresto flea and tick collars were introduced in 2012, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, including nearly 1,000 involving human harm.

The EPA is in charge of regulating products that contain pesticides. The agency has known about these incidents for years but has not informed the public of the potential risks associated with this product, said Karen McCormack, a retired EPA employee who worked as both a scientist and communications officer.

McCormack said the collars have the most incidents of any pesticide pet product she's ever seen.

"The EPA appears to be turning a blind eye to this problem, and after seven years of an increasing number of incidents, they are telling the public that they are continuing to monitor the situation," she said. "But I think this is a significant problem that needs to be addressed sooner rather than later."



The EPA declined to say how Seresto compares to other pet products. But in response to a question about whether the product is safe, an agency spokesperson said in an emailed statement that the two pesticides in Seresto have “been found eligible for continued registration” based on best available science, including incident data.

“No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk,” the spokesperson said. “The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.”

Amazon, where Seresto is the top-selling collar, also has received numerous complaints about the product from customers who detailed significant issues. Dozens of people over the years have claimed the collar caused skin rashes in their pet. Others said it led to neurological issues in their pets.

Despite the many warnings, Amazon has not removed the product from its online marketplace. Amazon did not respond to multiple requests for comment for this story.

This isn’t the first time that the EPA has failed to properly regulate flea and tick collars containing pesticides, said Miriam Rotkin-Ellman, a senior scientist at the Natural Resources Defense Council.

The NRDC filed a petition against the agency more than a decade ago over its approval of a different pesticide than the one used in Seresto that is linked to cancer and brain development issues in children.

In April 2020, a federal appeals court called the EPA's refusal to respond to NRDC's requests "nothing short of egregious" and told agency officials to make a decision on whether to ban the pesticide within 90 days. The EPA decided not to ban the pesticide, called tetrachlorvinphos. That pet collar continues to be sold under the brand name Hartz Ultraguard, Hartz InControl and Longlife.

NRDC has challenged that decision; that lawsuit is currently pending.

Even so, the number of incidents linked to that pesticide pales in comparison to those linked to Seresto. From 1992 to 2008, the EPA received about 4,600 incident reports regarding pet collars containing tetrachlorvinphos, including 363 deaths, according to EPA documents.

Broken down per year, that's 30 times fewer incidents and 10 times fewer deaths than Seresto.

And those are most likely an undercount, said Nathan Donley, a senior scientist at the Center for Biological Diversity and an expert on U.S. pesticide regulation. Donley said the number of reported incidents for Seresto is "just the tip of the iceberg."

In order to report an incident, a person has to make the connection between the collar and the issue with the dog, understand who to contact and how to report it, he said.

"Most of the time, people are not going to make the connection or they're not going to take an hour or so out of the day and figure out how to call and spend time on hold," Donley said.

He said the incident data creates lots of questions about EPA processes.

"My God, if this doesn't trigger a concern, that's a fundamental problem with the process," Donley said. "The fact that EPA has not done anything to alert the public that there might be an issue here, it strikes me as bordering on criminal. The EPA has this system in place to compile information and it's just collecting dust in some database."

A big business

Pet collars are big business. In its 2019 annual report, German agribusiness and pharmaceutical company Bayer reported revenue of more than \$300 million on Seresto alone.

The company sold its animal health division to Elanco Animal Health, a former subsidiary of Eli Lilly and Co., for \$7.6 billion in 2019. The deal was finalized in 2020. As part of the deal, Bayer received \$2.3 billion in Elanco stock, which the company said it would sell over time.

Bayer did not respond to multiple requests for comment.

Since being spun off as its own company in 2019, Elanco has lobbied the EPA quarterly on issues relating to animal health, according to the the nonprofit Center for Responsive Politics, which maintains a website tracking political contributions. Over two years, the company has spent \$1.6 million on lobbying, records show.

Keri McGrath, a spokeswoman for Elanco, said in an email the company “takes the safety of our products very seriously and thoroughly investigates potential concerns related to their use.” McGrath pointed out that regulatory authorities have approved the product in more than 80 countries, and the EPA is in the final stages of re-approving both pesticides. There is no timeline on the final decision.

McGrath said that global data shows that 1 in 568 users of Seresto have an incident and “the majority of these incident reports relate to non-serious effects such as application site disorders, e.g. a reddening of the skin or hair loss below the collar.”

“Keep in mind that the existence of an adverse event report does not necessarily mean the product caused the problem,” she said. “Causality between the observed signs and the use of the product is evaluated on a case-by-case basis. That said, every adverse event collected, regardless of causality, is reported to the authorities.”



The EPA did not respond to a request about how Seresto compared to other flea and tick collars in terms of incidents. The Midwest Center has filed a Freedom of Information request for the incident database, but that request has not yet been filled.

The extent of the damage is uncommon, said McCormack, the former EPA staffer.

“I’ve never seen any product that had 75,000 incidents,” McCormack said.

Seresto’s pesticides more toxic together

The EPA approved Seresto collars on March 16, 2012. The collars are designed to work for eight months.

Under the Federal Insecticide, Fungicide and Rodenticide Act, the EPA must determine a pesticide product will not cause “unreasonable effects on the environment.”

This determination requires weighing harms versus benefits, including assessments of risks to human health and the environment.

Seresto contains two pesticides: imidacloprid and flumethrin.

Imidacloprid belongs to the neonicotinoid class of insecticides, which are the most commonly used insecticides on crops in the U.S. Despite neonicotinoids being connected to massive die-offs of non-target insects such as bees and butterflies, the EPA proposed re-approving imidacloprid and

other class members last year. The pesticide is banned in the European Union for outdoor use but allowed in pet collars. There is also growing evidence that mammals can be harmed by these pesticides as well.

Flumethrin, EPA documents show, is only an active ingredient in one product: Seresto.

Like with most pesticides, the data supporting the registration of Seresto was conducted by the company that produced it, Bayer. The majority of the studies were looking at each pesticide individually.

However, a 2012 Bayer study found they have a “synergistic effect,” meaning they are more toxic together on fleas. The study found that the “unique pharmacological synergism” works as quickly as six hours to prevent ticks from attaching and feeding, preventing disease transmission.

Additionally, eight companion animal safety studies were conducted by Bayer looking at the effect of Seresto collars on domestic cats and dogs. The EPA used these studies to approve Seresto. The California Department of Pesticide Regulation took issue with the validity of two of the studies but approved the collars anyway.

Another issue could be a reaction of inactive ingredients, which are unknown and have caused problems in spot-on treatments, said Donley of the Center for Biological Diversity.

Donley, who has a doctorate in cell and developmental biology and is a former cancer researcher, said this “synergistic effect” likely extends to pets. He said he wasn’t sure what makes the two pesticides so likely to cause harm, but it is clear something is wrong with the product.

“You don’t even see these kinds of numbers with many agricultural chemicals,” Donley said.

“For whatever reason, this combination is just really nasty.”

History of unsafe pet treatments

There are currently 18 flea and tick collars on the market: three that are approved for both dogs and cats (including Seresto), 10 approved for dogs and five for cats, according to the National Pesticide Information Center.

In addition to allowing tetrachlorvinphos in pet collars despite evidence of its unsafety, the EPA also had approved the use of another pesticide linked to cancer and brain development problems – propoxur, which was sold under many brand names, including Bio Spot, Scratex Color, Zodiac, Sergeant’s Dual Action and Sentry Dual Action.

Rotkin-Ellman's research showed residues were high enough to pose a risk to children and adults who play with pets that were wearing the collars.

In April 2016, pesticide companies voluntarily agreed to stop using propoxur to help protect children's health. The brand names that used propoxur have switched to other active ingredients.

In addition, in 2010, the EPA increased label requirements and limited some inert ingredients in spot-on treatments, which are applied to a specific area of a pet. This happened after incident data showed the treatments were causing hundreds of pet deaths, as well as issues such as irritation, rashes and hair loss, gastrointestinal problems and seizures.

Collars have caused seizures, rashes in humans

It's not just pets that are being harmed, EPA documents show.

Between 2013 and 2018, 907 incidents were reported with humans, according to a September 2019 EPA assessment of human health risk.

The assessment determined that there were 19 severe incidents. Of those, eight people had dermal symptoms, such as a rash or hives, and seven had neurological symptoms, which included numbness and headaches.

Incidents listed by the EPA included:

- A 12-year-old boy who slept in a bed with a dog wearing a collar started having seizures and vomiting. He had to be hospitalized.
- A 67-year-old woman who slept in a bed with a dog wearing a collar reported having heart arrhythmia and fatigue.
- A 43-year-old man put collars on eight dogs and slept in the same bed as four of the dogs. A week later, he developed ear drainage and nasal and throat irritation and was told by a doctor that he had a hole in his ear drum. He removed the dog collars and the symptoms went away. He later reapplied the collars and the symptoms returned.

An October 2016 EPA bulletin responded to citizen concerns about children being exposed to Seresto, saying it had found exposure to the collars to be negligible.

"As stated in the precautions on the label, do not allow children to play with the collars. In addition, try to keep the pet away from young children for a day after putting on the collar to minimize exposure," the bulletin said.

“It’s really not just happening to animals. It’s happening to people who pet them as well,” Donley said. “I have two young kids who are all over our dog all the time. I can imagine how highly exposed people would be to residues.”

‘It’s just been a nightmare’

To Bomwell, the worst part was the lack of warning. Pierre had never been sick or had a seizure. He was just 9, so she thought he had half a decade left. Her last dog had died at 18. Plus, she felt like she was responsible. She was the one who put the collar on.

“It was so bizarre,” Bomwell said. “It’s just been a nightmare.”

Even if the EPA had not received tens of thousands of complaints, a cursory search of the web would find dozens of posts from pet owners warning others to be careful with the collars, including a letter to an animal doctor column in the St. Louis Post-Dispatch in 2013, a radio news story in New York in 2016 and extensive comments on pet forums.

Without the federal government stepping in, individuals are left in the dark. That’s something Ron Packard, of Brockton, Massachusetts, is hoping to address.

In the days after the death of his two dogs in June 2019, Packard did what any person looking for answers does: He went to the internet.

Two of Packard’s four dogs had recently had seizures on the same day, before becoming lethargic and vomiting and finally, refusing to eat. He brought them to the veterinarian, who couldn’t find a problem.

Within weeks, the two previously healthy cavachons, 10-year-old Danny and 5-year-old Dominic, were both dead.



The only thing Packard could figure out was both dogs had started wearing Seresto flea and tick collars a month before.

“Thirty-three and 54 days later, they're both dead,” Packard said.

Packard created a Facebook page, asking people who had similar issues to share their stories.

Today, the page fills up with pictures and stories like Packard's.

A dog starts wearing a collar. Within weeks, a dog will have a seizure, sometimes it will later die. Other stories aren't quite as extreme. Loss of hair around the neck. Lethargy.

Packard encourages everyone to report their story to the EPA.

“I don't want others to go through what we went through,” he said. “Every time I read the stories, it brings me back to my dogs. But if I can save a few pets, I can deal with it.”

This story is a collaboration between USA TODAY and the Midwest Center for Investigative Reporting. The center is an independent, nonprofit newsroom covering agribusiness, Big Ag and related issues. USA TODAY is funding a fellowship at the center for expanded coverage of agribusiness and its impact on communities.

Appointment

From: Goodis, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=50ED0B92DC4945B7A808FE8DBC9224F0-MICHAEL GOODIS]
Sent: 9/23/2016 3:40:00 PM
To: Davis, Kable [Davis.Kable@epa.gov]
Subject: Accepted: Seresto (flumethrin); 6(a)(2) letter discussion
Location: DCRoomPYS7621B/Potomac-Yard-One
Start: 9/26/2016 1:00:00 PM
End: 9/26/2016 1:30:00 PM
Show Time As: Busy

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 8/1/2016 1:51:03 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]
Subject: Seresto Briefing
Attachments: Seresto DD Briefing final draft.pptx
Location: DCRoomPYS7621B/Potomac-Yard-One
Start: 8/11/2016 1:00:00 PM
End: 8/11/2016 2:00:00 PM
Show Time As: Busy

Required Attendees: Goodis, Michael; Dan Rosenblatt; Echeverria, Marietta; Breeden-Alemi, Julie

IVB1 would like to brief the IO on the status of review for the incident data reported for Seresto (EPA Reg. No. 11556-155). The collar contains flumethrin and imidacloprid and is intended to control flea and ticks on cats and dogs for up to 8 months. The investigation into these incidents began last summer via a press inquiry. The product is currently pending registration in Canada.

Please find attached the slides from the DD briefing, which was given back in December. We will also take this opportunity to update you on the status of our review since the last briefing.



Seresto DD
Briefing final draf...

Appointment

From: Davis, Kable [Davis.Kable@epa.gov]
Sent: 8/11/2016 8:51:39 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Vogel, Dana [Vogel.Dana@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]

Subject: Seresto Discussion
Attachments: Seresto DD Briefing final draft.pptx
Location: DCRoomPYS7100/Potomac-Yard-One

Start: 8/16/2016 12:00:00 PM
End: 8/16/2016 1:00:00 PM
Show Time As: Busy

Required Attendees: Goodis, Michael; Vogel, Dana; Guilaran, Yu-Ting; Echeverria, Marietta; Arrington, Linda; Miller, David; Rossmeisl, Colleen; Recore, Shanna; Breeden-Alemi, Julie; Biscoe, Melanie

Everyone –

HED has been reviewing the incident data for Seresto (EPA Reg. No. 11556-155) for the last year and the objective of this meeting is to discuss the appropriate next steps. The product was pending review in Canada, however was withdrawn last week. To remind everyone of the situation, I have attached the slides from the DD briefing which was given last December.

I apologize for the early meeting, however this time worked best for the majority of people.



Seresto DD
Briefing final draf...

Appointment

From: Piansay, Maria [Piansay.Maria@epa.gov]
Sent: 9/13/2016 7:44:37 PM
To: Piansay, Maria [Piansay.Maria@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Vogel, Dana [Vogel.Dana@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]
CC: Knorr, Michele [Knorr.Michele@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]
Subject: Flumethrin Bayer Meeting
Location: DCRoomPYS9261/Potomac-Yard-One
Start: 9/22/2016 6:00:00 PM
End: 9/22/2016 7:00:00 PM
Show Time As: Busy

Required Attendees: Guilaran, Yu-Ting; Vogel, Dana; Rosenblatt, Daniel; Echeverria, Marietta; Miller, David; Rossmeisl, Colleen; Arrington, Linda; Davis, Kable; Biscoe, Melanie
Optional Attendees: Knorr, Michele; Goodis, Michael

Meeting Agenda from Bayer

1. To discuss status and timing of the documents EPA intends to release in September regarding Flumethrin and the Flumethrin-containing products;
2. To review timing of registration review for the Flumethrin-containing products and inclusion in the pyrethroid registration review;
3. To understand references and approach in these documents to Seresto;
4. To express Bayer's perspective on potential references to Flumethrin and Seresto;
5. To understand the anticipated scope of the registration review, and the expected schedule for the conduct of the review;
6. For Bayer to understand from the Agency its intentions and next steps in this process.

Attending from Bayer will be:

- Joyce Lee, President, Commercial Operations North America, Bayer Animal Health
- Robert Zolynas, Vice President Research and Development, North America, Bayer Animal Health
- Jessica Monachello, Assistant General Counsel Bayer Animal Health
- Roger R. Martella Jr., Outside Counsel, Sidley Austin LLP

Appointment

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 6/24/2019 5:06:07 PM
To: Aubee, Catherine [Aubee.Catherine@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Emerson, Vanessa [emerson.vanessa@epa.gov]; Eagle, Venus [Eagle.Venus@epa.gov]; Laws, Meredith [Laws.Meredith@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Snyderman, Steven [Snyderman.Steven@epa.gov]; Britton, Cathryn [Britton.Cathryn@epa.gov]; Kassa, Letu [Kassa.Letu@epa.gov]
CC: Reaves, Elissa [Reaves.Elissa@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Wilbur, Donald [Wilbur.Donald@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]; Niman, Aaron [niman.aaron@epa.gov]; Jones, Ricardo [Jones.Ricardo@epa.gov]; Fletcher, Rachel [fletcher.rachel@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Fertich, Elizabeth [fertich.elizabeth@epa.gov]; Miller, Robert [Miller.Robert@epa.gov]; Smith, Charles [Smith.Charles@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Colby, Deanna [colby.deanna@epa.gov]
Subject: Discuss Seresto Incident Profile
Attachments: Registrant Mtg Seresto 2019-07-16.pptx; Seresto Update on AE Rates.pdf
Location: DCRoomPYS9100/Potomac-Yard-One
Start: 7/16/2019 6:00:00 PM
End: 7/16/2019 7:00:00 PM
Show Time As: Busy

Required Attendees: Aubee, Catherine; Breeden-Alemi, Julie; Emerson, Vanessa; Eagle, Venus; Laws, Meredith; Miller, David; Snyderman, Steven; Britton, Cathryn; Kassa, Letu
Optional Attendees: Reaves, Elissa; Rossmeisl, Colleen; Wilbur, Donald; Goodis, Michael; Rosenblatt, Daniel; Davis, Donna; Niman, Aaron; Jones, Ricardo; Fletcher, Rachel; Biscoe, Melanie; Fertich, Elizabeth; Miller, Robert; Smith, Charles; Recore, Shanna; Colby, Deanna

This is a meeting with the registrant. The timeslot is now confirmed.

Suggested agenda

- 1) Brief introductions
- 2) Overview of Bayer/SCI trend reports (incidents v. sales over time)
- 3) Commonalities in narrative incident reports
- 4) Discussion and proposed next steps

External participants:

In person

- Jennifer Schofield (Bayer Animal Health, Regulatory Affairs EPA Manager)
- Rick Kingston (SafetyCall International, Pres. Regulatory and Scientific Affairs)

By phone

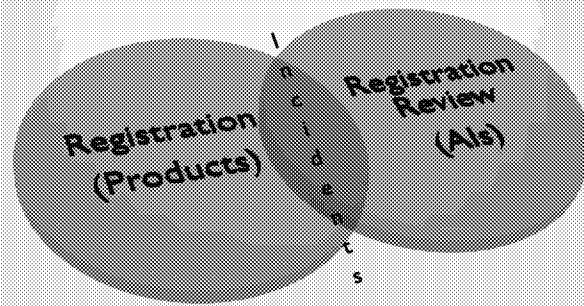
- Robert Zolynas (Bayer Animal Health, VP Research and Development)
- Daniel Keil (Bayer Animal Health, Senior Director Regulatory Affairs and Pharmacovigilance)
- Will Heeb (Bayer Animal Health, Manager Pharmacovigilance)
- Ahna Brutlag (SafetyCall International, Assoc. Director Veterinary Services)

Please delegate if you cannot attend and let me know if others should be invited.

Best,
Catherine
Chief, OPP RD IVB1



COLLABORATION



PRODUCT INFORMATION



EPA Registration No. 11556-155



PNR 1427 Insecticide

ABNs: Seresto Small Dog, Seresto Large Dog, Seresto Cat



Small collar may be labeled for use on dogs and/or cats

Large collar is only labeled for use on dogs



4.5% flumethrin *Trans Z-1/trans Z-2 ratio: max 66% trans Z-1 and min 34% trans Z-2
10% imidacloprid

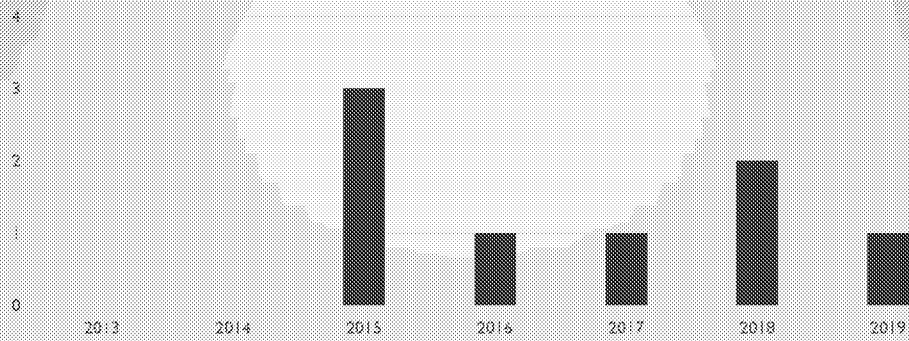


Unconditionally registered: March 16, 2012

Last stamped label: April 3, 2014

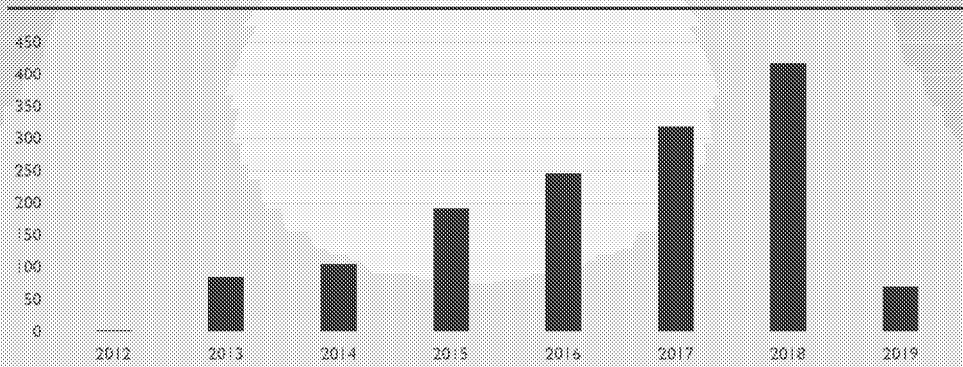
NARRATIVE REPORTS – DEATH OF ANIMAL

Via IST: Incident Screening Team



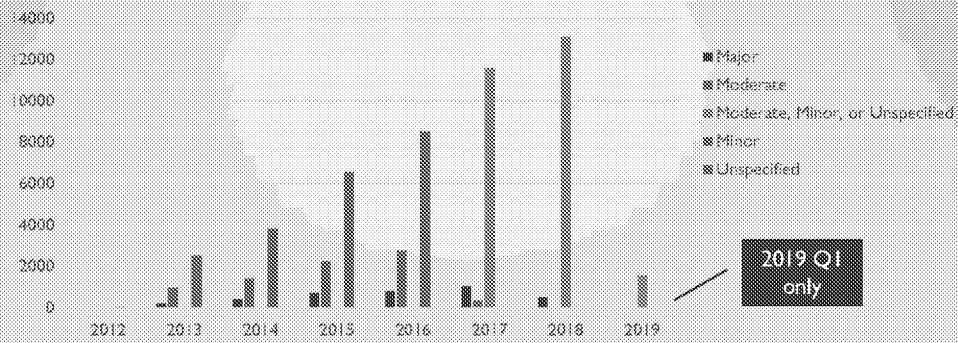
Data source: Seresto Individual Incident Report.xls; emailed June 26, 2019; c/o Robert Miller

AGGREGATE 6(A)(2) REPORTS – DEATH OF ANIMAL



Data source: Incident Data System Aggregate Incident Report Query; March 1, 2012 – July 10, 2019

AGGREGATE 6(A)(2) REPORTS – OTHER

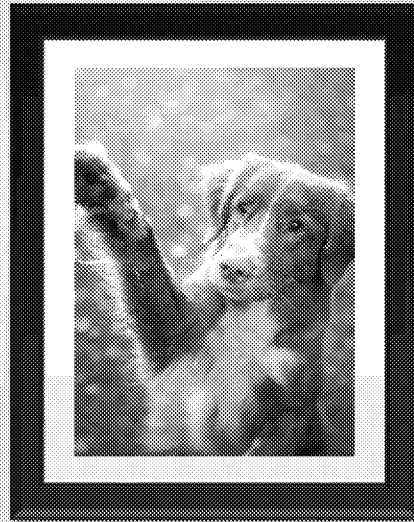


Data source: Incident Data System Aggregate Incident Report Query; March 1, 2012 – July 10, 2019

OTHER RECENT REPORTS

June 2019

- R5 veterinarian report of mastiff death, edema
- NPIC report of beagle seizures, was told mfr call center was down
- NPIC report of Labrador seizures
- NPIC report of mastiff bleeding skin after 1 week wearing collar

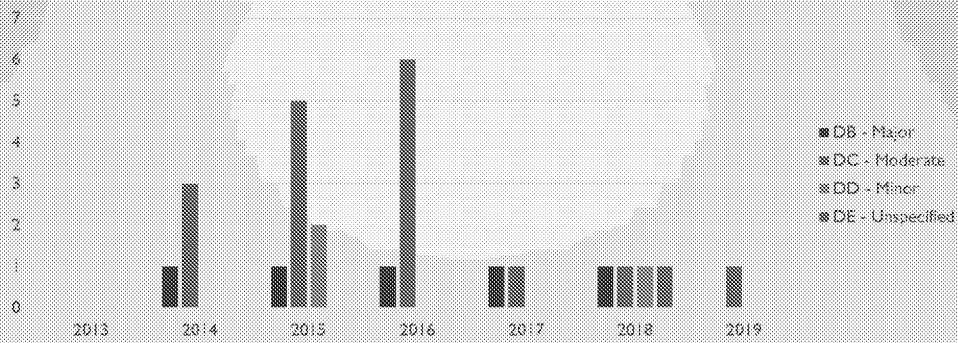


Since I have been in this role, the other two NPIC reports described neuro signs including seizures; one of the animals died a week later.



NARRATIVE REPORTS – OTHER

Via IST: Incident Screening Team



Data source: Seresto Individual Incident Report.xls; emailed June 26, 2019; c/o Robert Miller

This likely reflects that we rarely receive individual narratives for incident categories than death.

Appointment

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 7/3/2019 3:32:21 PM
To: Aubee, Catherine [Aubee.Catherine@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Emerson, Vanessa [emerson.vanessa@epa.gov]; Eagle, Venus [Eagle.Venus@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Snyderman, Steven [Snyderman.Steven@epa.gov]; Britton, Cathryn [Britton.Cathryn@epa.gov]; Kassa, Letu [Kassa.Letu@epa.gov]; Laws, Meredith [Laws.Meredith@epa.gov]
CC: Reaves, Elissa [Reaves.Elissa@epa.gov]; Rossmesl, Colleen [Rossmesl.Colleen@epa.gov]; Wilbur, Donald [Wilbur.Donald@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]; Niman, Aaron [niman.aaron@epa.gov]; Jones, Ricardo [Jones.Ricardo@epa.gov]; Fletcher, Rachel [fletcher.rachel@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Fertich, Elizabeth [fertich.elizabeth@epa.gov]; Myers, Tom [Myers.Tom@epa.gov]; Miller, Robert [Miller.Robert@epa.gov]; Smith, Charles [Smith.Charles@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]
Subject: Pre-brief: Seresto Incident Profile
Attachments: Internal pre-brief Seresto 2019-07-11.pptx; Seresto Update on AE Rates.pdf
Location: DCRoomPYS9100/Potomac-Yard-One
Start: 7/11/2019 2:00:00 PM
End: 7/11/2019 3:00:00 PM
Show Time As: Busy

Required Attendees: Aubee, Catherine; Breeden-Alemi, Julie; Emerson, Vanessa; Eagle, Venus; Laws, Meredith; Miller, David; Snyderman, Steven; Britton, Cathryn; Kassa, Letu
Optional Attendees: Reaves, Elissa; Rossmesl, Colleen; Wilbur, Donald; Goodis, Michael; Rosenblatt, Daniel; Davis, Donna; Niman, Aaron; Jones, Ricardo; Fletcher, Rachel; Biscoe, Melanie; Fertich, Elizabeth; Myers, Tom; Miller, Robert; Smith, Charles; Recore, Shanna

This is a pre-meeting for next week's meeting with the registrant (Tuesday, 7/16, @ 2pm in 9100).

We will review the information we have to date and identify any questions or messages that we would like to relay to the registrant.

Proposed agenda for the pre-meeting *(please let me know if you have additions or objections)*

- 6(a)(2) aggregate statistics
- Common themes in individual incident reports
- Registrant summary of sales-adjusted trends
- Concerns and thoughts on next steps
- Questions for the registrant

Best,
Catherine
Chief, OPP RD IVB1

Message

From: Goodis, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=50ED0B92DC4945B7A808FE8DBC9224F0-MICHAEL GOODIS]
Sent: 3/3/2021 2:15:28 PM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]
Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar

Ex. 6 Personal Privacy (PP)

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.

Ex. 6 Personal Privacy (PP)

From: Keigwin, Richard <Keigwin.Richard@epa.gov>
Sent: Wednesday, March 03, 2021 9:12 AM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Subject: Re: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar

Hmmm...

Rick Keigwin
Acting Deputy Assistant Administrator for Management
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Phone: **Ex. 6 Personal Privacy (PP)**
Sent from my iPhone (Please excuse typos!)

On Mar 3, 2021, at 9:11 AM, Goodis, Michael <Goodis.Michael@epa.gov> wrote:

Ex. 6 Personal Privacy (PP)

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.

Ex. 6 Personal Privacy (PP)

From: Keigwin, Richard <Keigwin.Richard@epa.gov>
Sent: Wednesday, March 03, 2021 9:02 AM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Subject: Re: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar

Sorry I wasn't able to get to the General yesterday. Was in a summit with ORD.

Rick Keigwin
Acting Deputy Assistant Administrator for Management
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Phone: Ex. 6 Personal Privacy (PP)
Sent from my iPhone (Please excuse typos!)

On Mar 3, 2021, at 8:58 AM, Goodis, Michael <Goodis.Michael@epa.gov> wrote:

Yep – brought it up during the OPP general. Michal OK with the FR going out as is.
Comms to make sure they have a desk statement prepared that will also address
potential criticism if it comes up.
Thanks for checking.

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.

Ex. 6 Personal Privacy (PP)

From: Keigwin, Richard <Keigwin.Richard@epa.gov>
Sent: Wednesday, March 03, 2021 8:56 AM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar

Did Ed get back to you on this?

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Tuesday, March 02, 2021 2:19 PM
To: Dennis, Allison <Dennis.Allison@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar

Ex. 5 Deliberative Process (DP)

Michael L. Goodis, P.E.
Acting Deputy Director for Programs

Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.

Ex. 6 Personal Privacy (PP)

From: Dennis, Allison <Dennis.Allison@epa.gov>
Sent: Tuesday, March 02, 2021 10:53 AM
To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>
Subject: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Head's up on this story. We're working up a statement regarding our incident data to use if needed. -Allison

https://apple.news/A78_uo4GIQWq_FP9GTVxg9w

Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Johnathan Hettinger
Midwest Center for Investigative Reporting

Rhonda Bomwell had never used a flea and tick collar before. Pierre, her 9-year-old Papillon service dog, was mostly an indoor animal.

Still, her veterinarian recommended she purchase one, so Bomwell went to the pet store near her home in Somerset, New Jersey, and selected Bayer's Seresto collar.

A day later, on June 2, 2020, Pierre had a seizure, collapsing while Bomwell was making dinner. Lying on his back, the dog stopped breathing and his eyes rolled back.

Bomwell tried giving him CPR. Then she called the police. An officer helped her lift the dog into her car, and she rushed him to the hospital. Pierre died before he could receive medical treatment. Bomwell didn't think to take off Pierre's collar.

“I just didn’t put it together,” she said.

Bomwell isn’t alone. Seresto, one of the most popular flea and tick collars in the country, has been linked to hundreds of pet deaths, tens of thousands of injured animals and hundreds of harmed humans, U.S. Environmental Protection Agency documents show.

Yet the EPA has done nothing to inform the public of the risks.

Seresto, developed by Bayer and now sold by Elanco, works by releasing small amounts of pesticide onto the animal for months at a time. The pesticide is supposed to kill fleas, ticks and other pests but be safe for cats and dogs.

<image001.jpg>

But thousands of pets are being harmed, according to federal documents obtained through a public records request from the Center for Biological Diversity, a nonprofit organization that watchdogs the EPA as part of its work to protect endangered species. The center provided the documents to the Midwest Center for Investigative Reporting.

Since Seresto flea and tick collars were introduced in 2012, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, including nearly 1,000 involving human harm.

The EPA is in charge of regulating products that contain pesticides. The agency has known about these incidents for years but has not informed the public of the potential risks associated with this product, said Karen McCormack, a retired EPA employee who worked as both a scientist and communications officer.

McCormack said the collars have the most incidents of any pesticide pet product she’s ever seen.

“The EPA appears to be turning a blind eye to this problem, and after seven years of an increasing number of incidents, they are telling the public that they are continuing to monitor the situation,” she said.

“But I think this is a significant problem that needs to be addressed sooner rather than later.”

<image002.jpg>

The EPA declined to say how Seresto compares to other pet products. But in response to a question about whether the product is safe, an agency spokesperson said in an emailed statement that the two pesticides in Seresto have “been found eligible for continued registration” based on best available science, including incident data.

“No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk,” the spokesperson said. “The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.”

Amazon, where Seresto is the top-selling collar, also has received numerous complaints about the product from customers who detailed significant issues. Dozens of people over the years have claimed the collar caused skin rashes in their pet. Others said it led to neurological issues in their pets.

Despite the many warnings, Amazon has not removed the product from its online marketplace. Amazon did not respond to multiple requests for comment for this story.

This isn’t the first time that the EPA has failed to properly regulate flea and tick collars containing pesticides, said Miriam Rotkin-Ellman, a senior scientist at the Natural Resources Defense Council.

The NRDC filed a petition against the agency more than a decade ago over its approval of a different pesticide than the one used in Seresto that is linked to cancer and brain development issues in children.

In April 2020, a federal appeals court called the EPA’s refusal to respond to NRDC’s requests “nothing short of egregious” and told agency officials to make a decision on whether to ban the pesticide within 90 days. The EPA decided not to ban the pesticide,

called tetrachlorvinphos. That pet collar continues to be sold under the brand name Hartz Ultraguard, Hartz InControl and Longlife.

NRDC has challenged that decision; that lawsuit is currently pending.

Even so, the number of incidents linked to that pesticide pales in comparison to those linked to Seresto. From 1992 to 2008, the EPA received about 4,600 incident reports regarding pet collars containing tetrachlorvinphos, including 363 deaths, according to EPA documents.

Broken down per year, that's 30 times fewer incidents and 10 times fewer deaths than Seresto.

And those are most likely an undercount, said Nathan Donley, a senior scientist at the Center for Biological Diversity and an expert on U.S. pesticide regulation. Donley said the number of reported incidents for Seresto is "just the tip of the iceberg."

In order to report an incident, a person has to make the connection between the collar and the issue with the dog, understand who to contact and how to report it, he said.

"Most of the time, people are not going to make the connection or they're not going to take an hour or so out of the day and figure out how to call and spend time on hold," Donley said.

He said the incident data creates lots of questions about EPA processes.

"My God, if this doesn't trigger a concern, that's a fundamental problem with the process," Donley said. "The fact that EPA has not done anything to alert the public that there might be an issue here, it strikes me as bordering on criminal. The EPA has this system in place to compile information and it's just collecting dust in some database."

A big business

Pet collars are big business. In its 2019 annual report, German agribusiness and pharmaceutical company Bayer reported revenue of more than \$300 million on Seresto alone.

The company sold its animal health division to Elanco Animal Health, a former subsidiary of Eli Lilly and Co., for \$7.6 billion in 2019. The deal was finalized in 2020. As part of the deal, Bayer received \$2.3 billion in Elanco stock, which the company said it would sell over time.

Bayer did not respond to multiple requests for comment.

Since being spun off as its own company in 2019, Elanco has lobbied the EPA quarterly on issues relating to animal health, according to the the nonprofit Center for Responsive Politics, which maintains a website tracking political contributions. Over two years, the company has spent \$1.6 million on lobbying, records show.

Keri McGrath, a spokeswoman for Elanco, said in an email the company “takes the safety of our products very seriously and thoroughly investigates potential concerns related to their use.” McGrath pointed out that regulatory authorities have approved the product in more than 80 countries, and the EPA is in the final stages of re-approving both pesticides. There is no timeline on the final decision.

McGrath said that global data shows that 1 in 568 users of Seresto have an incident and “the majority of these incident reports relate to non-serious effects such as application site disorders, e.g. a reddening of the skin or hair loss below the collar.”

“Keep in mind that the existence of an adverse event report does not necessarily mean the product caused the problem,” she said. “Causality between the observed signs and the use of the product is evaluated on a case-by-case basis. That said, every adverse event collected, regardless of causality, is reported to the authorities.”

<image003.jpg>

The EPA did not respond to a request about how Seresto compared to other flea and tick collars in terms of incidents. The Midwest Center has filed a Freedom of Information request for the incident database, but that request has not yet been filled.

The extent of the damage is uncommon, said McCormack, the former EPA staffer.

“I’ve never seen any product that had 75,000 incidents,” McCormack said.

Seresto’s pesticides more toxic together

The EPA approved Seresto collars on March 16, 2012. The collars are designed to work for eight months.

Under the Federal Insecticide, Fungicide and Rodenticide Act, the EPA must determine a pesticide product will not cause “unreasonable effects on the environment.”

This determination requires weighing harms versus benefits, including assessments of risks to human health and the environment.

Seresto contains two pesticides: imidacloprid and flumethrin.

Imidacloprid belongs to the neonicotinoid class of insecticides, which are the most commonly used insecticides on crops in the U.S. Despite neonicotinoids being connected to massive die-offs of non-target insects such as bees and butterflies, the EPA proposed re-approving imidacloprid and other class members last year. The pesticide is banned in the European Union for outdoor use but allowed in pet collars. There is also growing evidence that mammals can be harmed by these pesticides as well.

Flumethrin, EPA documents show, is only an active ingredient in one product: Seresto.

Like with most pesticides, the data supporting the registration of Seresto was conducted by the company that produced it, Bayer. The majority of the studies were looking at each pesticide individually.

However, a 2012 Bayer study found they have a “synergistic effect,” meaning they are more toxic together on fleas. The study found that the “unique pharmacological synergism” works as quickly as six hours to

prevent ticks from attaching and feeding, preventing disease transmission.

Additionally, eight companion animal safety studies were conducted by Bayer looking at the effect of Seresto collars on domestic cats and dogs. The EPA used these studies to approve Seresto. The California Department of Pesticide Regulation took issue with the validity of two of the studies but approved the collars anyway.

Another issue could be a reaction of inactive ingredients, which are unknown and have caused problems in spot-on treatments, said Donley of the Center for Biological Diversity.

Donley, who has a doctorate in cell and developmental biology and is a former cancer researcher, said this “synergistic effect” likely extends to pets. He said he wasn’t sure what makes the two pesticides so likely to cause harm, but it is clear something is wrong with the product.

“You don’t even see these kinds of numbers with many agricultural chemicals,” Donley said.

“For whatever reason, this combination is just really nasty.”

History of unsafe pet treatments

There are currently 18 flea and tick collars on the market: three that are approved for both dogs and cats (including Seresto), 10 approved for dogs and five for cats, according to the National Pesticide Information Center.

In addition to allowing tetrachlorvinphos in pet collars despite evidence of its unsafety, the EPA also had approved the use of another pesticide linked to cancer and brain development problems – propoxur, which was sold under many brand names, including Bio Spot, Scratex Color, Zodiac, Sergeant’s Dual Action and Sentry Dual Action.

Rotkin-Ellman’s research showed residues were high enough to pose a risk to children and adults who play with pets that were wearing the collars.

In April 2016, pesticide companies voluntarily agreed to stop using propoxur to help protect children's health. The brand names that used propoxur have switched to other active ingredients.

In addition, in 2010, the EPA increased label requirements and limited some inert ingredients in spot-on treatments, which are applied to a specific area of a pet. This happened after incident data showed the treatments were causing hundreds of pet deaths, as well as issues such as irritation, rashes and hair loss, gastrointestinal problems and seizures.

Collars have caused seizures, rashes in humans

It's not just pets that are being harmed, EPA documents show.

Between 2013 and 2018, 907 incidents were reported with humans, according to a September 2019 EPA assessment of human health risk.

The assessment determined that there were 19 severe incidents. Of those, eight people had dermal symptoms, such as a rash or hives, and seven had neurological symptoms, which included numbness and headaches.

Incidents listed by the EPA included:

- A 12-year-old boy who slept in a bed with a dog wearing a collar started having seizures and vomiting. He had to be hospitalized.
- A 67-year-old woman who slept in a bed with a dog wearing a collar reported having heart arrhythmia and fatigue.
- A 43-year-old man put collars on eight dogs and slept in the same bed as four of the dogs. A week later, he developed ear drainage and nasal and throat irritation and was told by a doctor that he had a hole in his ear drum. He removed the dog collars and the symptoms went away. He later reapplied the collars and the symptoms returned.

An October 2016 EPA bulletin responded to citizen concerns about children being exposed to Seresto, saying it had found exposure to the collars to be negligible.

“As stated in the precautions on the label, do not allow children to play with the collars. In addition, try to keep the pet away from young children for a day after putting on the collar to minimize exposure,” the bulletin said.

“It’s really not just happening to animals. It’s happening to people who pet them as well,” Donley said. “I have two young kids who are all over our dog all the time. I can imagine how highly exposed people would be to residues.”

‘It’s just been a nightmare’

To Bomwell, the worst part was the lack of warning. Pierre had never been sick or had a seizure. He was just 9, so she thought he had half a decade left. Her last dog had died at 18. Plus, she felt like she was responsible. She was the one who put the collar on.

“It was so bizarre,” Bomwell said. “It’s just been a nightmare.”

Even if the EPA had not received tens of thousands of complaints, a cursory search of the web would find dozens of posts from pet owners warning others to be careful with the collars, including a letter to an animal doctor column in the St. Louis Post-Dispatch in 2013, a radio news story in New York in 2016 and extensive comments on pet forums.

Without the federal government stepping in, individuals are left in the dark. That’s something Ron Packard, of Brockton, Massachusetts, is hoping to address.

In the days after the death of his two dogs in June 2019, Packard did what any person looking for answers does: He went to the internet.

Two of Packard’s four dogs had recently had seizures on the same day, before becoming lethargic and vomiting and finally, refusing to eat. He brought them to the veterinarian, who couldn’t find a problem.

Within weeks, the two previously healthy cavachons, 10-year-old Danny and 5-year-old Dominic, were both dead.

<image004.jpg>

The only thing Packard could figure out was both dogs had started wearing Seresto flea and tick collars a month before.

“Thirty-three and 54 days later, they’re both dead,” Packard said.

Packard created a Facebook page, asking people who had similar issues to share their stories.

Today, the page fills up with pictures and stories like Packard’s.

A dog starts wearing a collar. Within weeks, a dog will have a seizure, sometimes it will later die. Other stories aren’t quite as extreme. Loss of hair around the neck. Lethargy.

Packard encourages everyone to report their story to the EPA.

“I don’t want others to go through what we went through,” he said.

“Every time I read the stories, it brings me back to my dogs. But if I can save a few pets, I can deal with it.”

This story is a collaboration between USA TODAY and the Midwest Center for Investigative Reporting. The center is an independent, nonprofit newsroom covering agribusiness, Big Ag and related issues. USA TODAY is funding a fellowship at the center for expanded coverage of agribusiness and its impact on communities.

Message

From: Goodis, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=50ED0B92DC4945B7A808FE8DBC9224F0-MICHAEL GOODIS]
Sent: 6/20/2019 9:54:24 PM
To: Aubee, Catherine [Aubee.Catherine@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]
Subject: Fwd: Noteworthy Case from NPIC (Seresto collar)
Attachments: image003.png; ATT00001.htm; 2019_4456,4443.pdf; ATT00002.htm

FYI

Is this useful information?

Sent from my iPhone

Begin forwarded message:

From: "Parrott, Patricia" <parrott.patricia@epa.gov>
Date: June 20, 2019 at 3:41:00 PM EDT
To: "Keigwin, Richard" <Keigwin.Richard@epa.gov>, "Goodis, Michael" <Goodis.Michael@epa.gov>
Cc: "Davis, Donna" <Davis.Donna@epa.gov>, "Miller, Wynne" <Miller.Wynne@epa.gov>, "Rosenblatt, Daniel" <Rosenblatt.Dan@epa.gov>
Subject: FW: Noteworthy Case from NPIC (Seresto collar)

FYI: Dog collar incident

From: Rivera-Lupianez, Ana
Sent: Thursday, June 20, 2019 3:32 PM
To: Chen, Jonathan <Chen.Jonathan@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>; Mastrota, Nicholas <Mastrota.Nicholas@epa.gov>; Panger, Melissa <Panger.Melissa@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Rivera-Lupianez, Ana <Rivera-Lupianez.Ana@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>
Cc: Parrott, Patricia <parrott.patricia@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>; Han, Kaythi <Han.Kaythi@epa.gov>; Hopkins, Yvette <Hopkins.Yvette@epa.gov>; Lloyd, Matthew <Lloyd.Matthew@epa.gov>
Subject: FW: Noteworthy Case from NPIC (Seresto collar)

Hi,

Pet incident involving a Seresto flea collar. Please forward to interested staff.

Thanks,
Ana

Ana Rivera-Lupiáñez
Pesticide Worker Safety Programs
Office of Pesticide Programs
Environmental Protection Agency
rivera-lupianez.ana@epa.gov
(703) 308-6841

From: Hughes, Cameron C <Cameron.Hughes@oregonstate.edu>
Sent: Wednesday, June 19, 2019 11:20 AM
To: Rivera-Lupianez, Ana <Rivera-Lupianez.Ana@epa.gov>
Cc: Cross, Amy S <Amy.Cross@oregonstate.edu>; Sean Ross <rossse@oregonstate.edu>
Subject: Re: Noteworthy Case from NPIC

Hi Ana,

Attached is another noteworthy case about Seresto flea collars.

Thank you,

Cameron

--

Cameron Hughes

Knowledge Management & Project Specialist
National Pesticide Information Center
Pesticide Educational Resources Collaborative
Oregon State University
310 Weniger Hall
Corvallis, OR 97331
(541) 737-6123

On Tue, Jun 18, 2019 at 2:58 PM Hughes, Cameron C <Cameron.Hughes@oregonstate.edu> wrote:

Hi Ana,

We had a sentinel report today in Idaho state. I've attached the report.

Please let us know if you have any questions,

Cam

--

Cameron Hughes

Knowledge Management & Project Specialist
National Pesticide Information Center
Pesticide Educational Resources Collaborative
Oregon State University
310 Weniger Hall
Corvallis, OR 97331
(541) 737-6123

Date: 6/14/2019

City, State: SAPPHIRE, NC

Narrative for log 4456: Caller wishing to file a report after his dog had a reaction to a Seresto flea collar, EPA registration number 11556-155 (active ingredients imidacloprid, flumethrin). Caller reported that the dog (6-year-old, 67 lb., intact male purebred Labrador) had been wearing the collar for about 9 months or a year, and then in March (three months ago) had a large seizure in their home. Caller reported that he immediately removed the collar, and about six weeks later the dog had another seizure. Caller reported that the dog is a hunting dog and is in excellent physical health. Caller reported that he has been working with his veterinarian who also suspects that the collar was the source of the seizures. Caller reported he has been detoxing the dog for a couple months now and hasn't had any further seizures. Caller reported he has seen extensive reports of reactions to this specific type of flea collar and is shocked that the EPA has not stopped it from being sold.

Discussed NPIC services, including not working for the EPA directly. Discussed NPIC incident documentation and reporting to the EPA. Discussed that reporting adverse reactions to the manufacturer is an additional method to report when incidents occur. Discussed that products are also registered at a state level and provided the State Lead Pesticide Agency as a resource for reporting his concerns regarding the availability of this product. Caller sent follow-up email, see log 4443.

Narrative for log 4443: Email Received:

Here is the web contact that will show you what a veterinarian has to say about this poisonous dog collar

I'm a relatively intelligent human being with a good education and I can't for the life of me figure out why I let my dog wear this Horrible poisonous flea collar.

As it turns out these pesticides are very potent and do have side effects such as seizures

You will see a chart in this report that shows you how many people have reported this product that should not be on the market in the first place.

This is just about money not the welfare of our beloved pets.

My dog comes from a long line of field trial champions. This animal is as fit as an animal can be. This poisonous product turned him into a quivering mass and for a while I was afraid, I was going to lose him and by the way other dogs have died from this stuff

I'd really like to get the guy on the phone that authorizes this product to be sold without any proper warnings that your pet may be turned into a giant quivering mass.



2019 REFERRAL TO EPA

LOG: 4456, 4443

Let me know if I can be of any assistance while I look for other ways to warn other people that this product is dangerous, and it should not be put anywhere on a pet containing these kinds of pesticides

Thanks for your help today I really appreciate it and best regards
[omitted]

<http://healthydogworkshop.com/why-i-dont-recommend-seresto-collars/>

Email Response:

No response necessary, sending follow up email from earlier call log 4456. Log 4443.

Message

From: Goodis, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=50ED0B92DC4945B7A808FE8DBC9224F0-MICHAEL GOODIS]
Sent: 3/2/2021 4:32:35 PM
To: Messina, Edward [Messina.Edward@epa.gov]
Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.
Attachments: RE: OPP IO REVIEW: Response - Seresto.docx

Flag: Follow up

The full response to the Qs are attached.

Background

FIFRA is the law under which EPA regulates products for pests of pets. Under the law, EPA must make a determination that the product will not cause “unreasonable adverse effects on the environment,” defined in FIFRA 2(bb) as (in part) “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.” Thus, the benefits of a product must be weighed against the risks.

No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk. The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.

EPA evaluates pesticide products intended for treatment of pets based on the directions for use on the product label, which must be followed under federal law. Evaluations for pet products like shampoos, collars and spot-ons rely upon data on companion animal safety, efficacy and safety for humans who may be exposed as a result of product use. These assessments help ensure that people and pets are protected when pet pesticide treatments are used as directed.

Manufacturers are required under law to report adverse incident information to EPA. Individuals may report incidents potentially associated with use of an EPA-registered product by contacting the product manufacturer, their state lead pesticide agency, the National Pesticide Information Center, or by contacting EPA directly.

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
571-309-5497 (cell)

From: Messina, Edward <Messina.Edward@epa.gov>
Sent: Tuesday, March 02, 2021 11:16 AM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Was this in our press response?

.Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.”

Ed Messina, Esq.
Acting Office Director
Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
p: (703) 347-0209

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Tuesday, March 2, 2021 11:12 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>
Subject: FW: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

FYI

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
571-309-5497 (cell)

From: Dennis, Allison <Dennis.Allison@epa.gov>
Sent: Tuesday, March 02, 2021 10:53 AM
To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>
Subject: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Head's up on this story. We're working up a statement regarding our incident data to use if needed. -Allison

https://apple.news/A78_uo4GiQWq_FP9GTVxg9w

Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Johnathan Hettinger

Rhonda Bomwell had never used a flea and tick collar before. Pierre, her 9-year-old Papillon service dog, was mostly an indoor animal.

Still, her veterinarian recommended she purchase one, so Bomwell went to the pet store near her home in Somerset, New Jersey, and selected Bayer's Seresto collar.

A day later, on June 2, 2020, Pierre had a seizure, collapsing while Bomwell was making dinner. Lying on his back, the dog stopped breathing and his eyes rolled back.

Bomwell tried giving him CPR. Then she called the police. An officer helped her lift the dog into her car, and she rushed him to the hospital. Pierre died before he could receive medical treatment. Bomwell didn't think to take off Pierre's collar.

"I just didn't put it together," she said.

Bomwell isn't alone. Seresto, one of the most popular flea and tick collars in the country, has been linked to hundreds of pet deaths, tens of thousands of injured animals and hundreds of harmed humans, [U.S. Environmental Protection Agency documents show](#).

Yet the EPA has done nothing to inform the public of the risks.

Seresto, developed by Bayer and now sold by Elanco, works by releasing small amounts of pesticide onto the animal for months at a time. The pesticide is supposed to kill fleas, ticks and other pests but be safe for cats and dogs.



But thousands of pets are being harmed, according to federal documents obtained through a public records request from the Center for Biological Diversity, a nonprofit organization that watchdogs the EPA as part of its work to protect endangered species. The center provided the documents to the Midwest Center for Investigative Reporting.

Since Seresto flea and tick collars were introduced in 2012, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, including nearly 1,000 involving human harm.

The EPA is in charge of regulating products that contain pesticides. The agency has known about these incidents for years but has not informed the public of the potential risks associated with this product, said Karen McCormack, a retired EPA employee who worked as both a scientist and communications officer.

McCormack said the collars have the most incidents of any pesticide pet product she's ever seen.

"The EPA appears to be turning a blind eye to this problem, and after seven years of an increasing number of incidents, they are telling the public that they are continuing to monitor the situation," she said. "But I think this is a significant problem that needs to be addressed sooner rather than later."



The EPA declined to say how Seresto compares to other pet products. But in response to a question about whether the product is safe, an agency spokesperson said in an emailed statement that the two pesticides in Seresto have “been found eligible for continued registration” based on best available science, including incident data.

“No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk,” the spokesperson said. “The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.”

Amazon, where Seresto is the top-selling collar, also has received numerous complaints about the product from customers who detailed significant issues. Dozens of people over the years have claimed the collar caused skin rashes in their pet. Others said it led to neurological issues in their pets.

Despite the many warnings, Amazon has not removed the product from its online marketplace. Amazon did not respond to multiple requests for comment for this story.

This isn’t the first time that the EPA has failed to properly regulate flea and tick collars containing pesticides, said Miriam Rotkin-Ellman, a senior scientist at the Natural Resources Defense Council.

The NRDC filed a petition against the agency more than a decade ago over its approval of a different pesticide than the one used in Seresto that is linked to cancer and brain development issues in children.

In April 2020, a federal appeals court called the EPA's refusal to respond to NRDC's requests "nothing short of egregious" and told agency officials to make a decision on whether to ban the pesticide within 90 days. The EPA decided not to ban the pesticide, called tetrachlorvinphos. That pet collar continues to be sold under the brand name Hartz Ultraguard, Hartz InControl and Longlife.

NRDC has challenged that decision; that lawsuit is currently pending.

Even so, the number of incidents linked to that pesticide pales in comparison to those linked to Seresto. From 1992 to 2008, the EPA received about 4,600 incident reports regarding pet collars containing tetrachlorvinphos, including 363 deaths, according to EPA documents.

Broken down per year, that's 30 times fewer incidents and 10 times fewer deaths than Seresto.

And those are most likely an undercount, said Nathan Donley, a senior scientist at the Center for Biological Diversity and an expert on U.S. pesticide regulation. Donley said the number of reported incidents for Seresto is "just the tip of the iceberg."

In order to report an incident, a person has to make the connection between the collar and the issue with the dog, understand who to contact and how to report it, he said.

"Most of the time, people are not going to make the connection or they're not going to take an hour or so out of the day and figure out how to call and spend time on hold," Donley said.

He said the incident data creates lots of questions about EPA processes.

"My God, if this doesn't trigger a concern, that's a fundamental problem with the process," Donley said. "The fact that EPA has not done anything to alert the public that there might be an issue here, it strikes me as bordering on criminal. The EPA has this system in place to compile information and it's just collecting dust in some database."

A big business

Pet collars are big business. In its 2019 annual report, German agribusiness and pharmaceutical company Bayer reported revenue of more than \$300 million on Seresto alone.

The company sold its animal health division to Elanco Animal Health, a former subsidiary of Eli Lilly and Co., for \$7.6 billion in 2019. The deal was finalized in 2020. As part of the deal, Bayer received \$2.3 billion in Elanco stock, which the company said it would sell over time.

Bayer did not respond to multiple requests for comment.

Since being spun off as its own company in 2019, Elanco has lobbied the EPA quarterly on issues relating to animal health, according to the the nonprofit Center for Responsive Politics, which maintains a website tracking political contributions. Over two years, the company has spent \$1.6 million on lobbying, records show.

Keri McGrath, a spokeswoman for Elanco, said in an email the company “takes the safety of our products very seriously and thoroughly investigates potential concerns related to their use.” McGrath pointed out that regulatory authorities have approved the product in more than 80 countries, and the EPA is in the final stages of re-approving both pesticides. There is no timeline on the final decision.

McGrath said that global data shows that 1 in 568 users of Seresto have an incident and “the majority of these incident reports relate to non-serious effects such as application site disorders, e.g. a reddening of the skin or hair loss below the collar.”

“Keep in mind that the existence of an adverse event report does not necessarily mean the product caused the problem,” she said. “Causality between the observed signs and the use of the product is evaluated on a case-by-case basis. That said, every adverse event collected, regardless of causality, is reported to the authorities.”



The EPA did not respond to a request about how Seresto compared to other flea and tick collars in terms of incidents. The Midwest Center has filed a Freedom of Information request for the incident database, but that request has not yet been filled.

The extent of the damage is uncommon, said McCormack, the former EPA staffer.

“I’ve never seen any product that had 75,000 incidents,” McCormack said.

Seresto’s pesticides more toxic together

The EPA approved Seresto collars on March 16, 2012. The collars are designed to work for eight months.

Under the Federal Insecticide, Fungicide and Rodenticide Act, the EPA must determine a pesticide product will not cause “unreasonable effects on the environment.”

This determination requires weighing harms versus benefits, including assessments of risks to human health and the environment.

Seresto contains two pesticides: imidacloprid and flumethrin.

Imidacloprid belongs to the neonicotinoid class of insecticides, which are the most commonly used insecticides on crops in the U.S. Despite neonicotinoids being connected to massive die-offs of non-target insects such as bees and butterflies, the EPA proposed re-approving imidacloprid and

other class members last year. The pesticide is banned in the European Union for outdoor use but allowed in pet collars. There is also growing evidence that mammals can be harmed by these pesticides as well.

Flumethrin, EPA documents show, is only an active ingredient in one product: Seresto.

Like with most pesticides, the data supporting the registration of Seresto was conducted by the company that produced it, Bayer. The majority of the studies were looking at each pesticide individually.

However, a 2012 Bayer study found they have a “synergistic effect,” meaning they are more toxic together on fleas. The study found that the “unique pharmacological synergism” works as quickly as six hours to prevent ticks from attaching and feeding, preventing disease transmission.

Additionally, eight companion animal safety studies were conducted by Bayer looking at the effect of Seresto collars on domestic cats and dogs. The EPA used these studies to approve Seresto. The California Department of Pesticide Regulation took issue with the validity of two of the studies but approved the collars anyway.

Another issue could be a reaction of inactive ingredients, which are unknown and have caused problems in spot-on treatments, said Donley of the Center for Biological Diversity.

Donley, who has a doctorate in cell and developmental biology and is a former cancer researcher, said this “synergistic effect” likely extends to pets. He said he wasn’t sure what makes the two pesticides so likely to cause harm, but it is clear something is wrong with the product.

“You don’t even see these kinds of numbers with many agricultural chemicals,” Donley said.

“For whatever reason, this combination is just really nasty.”

History of unsafe pet treatments

There are currently 18 flea and tick collars on the market: three that are approved for both dogs and cats (including Seresto), 10 approved for dogs and five for cats, according to the National Pesticide Information Center.

In addition to allowing tetrachlorvinphos in pet collars despite evidence of its unsafety, the EPA also had approved the use of another pesticide linked to cancer and brain development problems – propoxur, which was sold under many brand names, including Bio Spot, Scratex Color, Zodiac, Sergeant’s Dual Action and Sentry Dual Action.

Rotkin-Ellman's research showed residues were high enough to pose a risk to children and adults who play with pets that were wearing the collars.

In April 2016, pesticide companies voluntarily agreed to stop using propoxur to help protect children's health. The brand names that used propoxur have switched to other active ingredients.

In addition, in 2010, the EPA increased label requirements and limited some inert ingredients in spot-on treatments, which are applied to a specific area of a pet. This happened after incident data showed the treatments were causing hundreds of pet deaths, as well as issues such as irritation, rashes and hair loss, gastrointestinal problems and seizures.

Collars have caused seizures, rashes in humans

It's not just pets that are being harmed, EPA documents show.

Between 2013 and 2018, 907 incidents were reported with humans, according to a September 2019 EPA assessment of human health risk.

The assessment determined that there were 19 severe incidents. Of those, eight people had dermal symptoms, such as a rash or hives, and seven had neurological symptoms, which included numbness and headaches.

Incidents listed by the EPA included:

- A 12-year-old boy who slept in a bed with a dog wearing a collar started having seizures and vomiting. He had to be hospitalized.
- A 67-year-old woman who slept in a bed with a dog wearing a collar reported having heart arrhythmia and fatigue.
- A 43-year-old man put collars on eight dogs and slept in the same bed as four of the dogs. A week later, he developed ear drainage and nasal and throat irritation and was told by a doctor that he had a hole in his ear drum. He removed the dog collars and the symptoms went away. He later reapplied the collars and the symptoms returned.

An October 2016 EPA bulletin responded to citizen concerns about children being exposed to Seresto, saying it had found exposure to the collars to be negligible.

"As stated in the precautions on the label, do not allow children to play with the collars. In addition, try to keep the pet away from young children for a day after putting on the collar to minimize exposure," the bulletin said.

“It’s really not just happening to animals. It’s happening to people who pet them as well,” Donley said. “I have two young kids who are all over our dog all the time. I can imagine how highly exposed people would be to residues.”

‘It’s just been a nightmare’

To Bomwell, the worst part was the lack of warning. Pierre had never been sick or had a seizure. He was just 9, so she thought he had half a decade left. Her last dog had died at 18. Plus, she felt like she was responsible. She was the one who put the collar on.

“It was so bizarre,” Bomwell said. “It’s just been a nightmare.”

Even if the EPA had not received tens of thousands of complaints, a cursory search of the web would find dozens of posts from pet owners warning others to be careful with the collars, including a letter to an animal doctor column in the St. Louis Post-Dispatch in 2013, a radio news story in New York in 2016 and extensive comments on pet forums.

Without the federal government stepping in, individuals are left in the dark. That’s something Ron Packard, of Brockton, Massachusetts, is hoping to address.

In the days after the death of his two dogs in June 2019, Packard did what any person looking for answers does: He went to the internet.

Two of Packard’s four dogs had recently had seizures on the same day, before becoming lethargic and vomiting and finally, refusing to eat. He brought them to the veterinarian, who couldn’t find a problem.

Within weeks, the two previously healthy cavachons, 10-year-old Danny and 5-year-old Dominic, were both dead.



The only thing Packard could figure out was both dogs had started wearing Seresto flea and tick collars a month before.

“Thirty-three and 54 days later, they're both dead,” Packard said.

Packard created a Facebook page, asking people who had similar issues to share their stories.

Today, the page fills up with pictures and stories like Packard's.

A dog starts wearing a collar. Within weeks, a dog will have a seizure, sometimes it will later die. Other stories aren't quite as extreme. Loss of hair around the neck. Lethargy.

Packard encourages everyone to report their story to the EPA.

“I don't want others to go through what we went through,” he said. “Every time I read the stories, it brings me back to my dogs. But if I can save a few pets, I can deal with it.”

This story is a collaboration between USA TODAY and the Midwest Center for Investigative Reporting. The center is an independent, nonprofit newsroom covering agribusiness, Big Ag and related issues. USA TODAY is funding a fellowship at the center for expanded coverage of agribusiness and its impact on communities.

Message

From: Ozmen, Shamus [Ozmen.Shamus@epa.gov]
Sent: 2/2/2021 3:24:08 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]; Overbey, Dian [Overbey.Dian@epa.gov]; Siedschlag, Gregory [Siedschlag.Gregory@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]
CC: Dinkins, Darlene [Dinkins.Darlene@epa.gov]
Subject: RE: OPP IO REVIEW: Response - Seresto.docx
Attachments: Response - Seresto updated 2-2 cleaned.docx; Response - Seresto updated 2-2 tracked.docx

Thanks Mike and Dian. I'll move this forward to Allison.

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Tuesday, February 2, 2021 10:15 AM
To: Overbey, Dian <Overbey.Dian@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>
Cc: Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Subject: RE: OPP IO REVIEW: Response - Seresto.docx

That works – thanks

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
571-309-5497 (cell)

From: Overbey, Dian <Overbey.Dian@epa.gov>
Sent: Tuesday, February 02, 2021 10:06 AM
To: Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>
Cc: Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Subject: RE: OPP IO REVIEW: Response - Seresto.docx

Hi.

Ex. 5 Deliberative Process (DP)

Dian

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Monday, February 01, 2021 5:27 PM
To: Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>
Cc: Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Overbey, Dian <Overbey.Dian@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Subject: RE: OPP IO REVIEW: Response - Seresto.docx

Thanks Greg

Ex. 5 Deliberative Process (DP)

No other comments - this was not an easy one to prepare. Thanks

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
571-309-5497 (cell)

From: Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>
Sent: Monday, February 01, 2021 3:31 PM
To: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Overbey, Dian <Overbey.Dian@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Subject: OPP IO REVIEW: Response - Seresto.docx
Importance: High

Hi Ed and Mike,

Press inquiry on pet collars attached. Deadline is COB, so please review at your earliest convenience. Apologies for the short notice.

Thanks,
Greg

1. **I am working on a story about EPA incident data surrounding Seresto collars. It is my understanding that there have been a significant amount of incidents surrounding the pesticides in the collars, and I had some questions.**

According to a records request of EPA documents, there have been at least 75,000 incident reports involving pets, including 1,698 deaths. Is this a high number? Why is it still sold? Is there any sort of threshold for removing the collar from the market?

EPA has re-evaluated flumethrin and imidacloprid, the active ingredients in the Seresto collar, as part of its registration review program. During registration review, the Agency looks at each active ingredient to ensure that it continues to meet the legal standard for registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and other applicable statutes.

EPA has evaluated numerous pet incidents since flumethrin's registration in 2012; however, a comparative assessment of pet incidents across all registered pet products based on usage data is not available.

Ex. 5 Deliberative Process (DP)

Additional information on this project can be found at [[HYPERLINK "https://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects"](https://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects)]. As additional information is gathered through this project, EPA intends to evaluate how this analysis informs the use of other pet products generally, including those that contain pyrethroids, to determine if additional changes are needed to pet product registrations, such as the Seresto collar registration.

Background

FIFRA is the law under which EPA regulates products for pests of pets. Under the law, EPA must make a determination that the product will not cause “unreasonable adverse effects on the environment,” defined in FIFRA 2(bb) as (in part) “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.” Thus, the benefits of a product must be weighed against the risks.

No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk. The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.

EPA evaluates pesticide products intended for treatment of pets based on the directions for use on the product label, which must be followed under federal law. Evaluations for pet products like shampoos, collars and spot-ons rely upon data on companion animal safety, efficacy and safety for humans who may be exposed as a result of product use. These assessments help ensure that people and pets are protected when pet pesticide treatments are used as directed.

Manufacturers are required under law to report adverse incident information to EPA. Individuals may report incidents potentially associated with use of an EPA-registered product by contacting the product manufacturer, their state lead pesticide agency, the National Pesticide Information Center, or by contacting EPA directly.

2. **It is my understanding that these incidents do not include the main incident reporting system, which likely has additional incidents. Do you have more information about the number of incidents?**

This information is taken from EPA's Incident Data System (IDS), which is the main system in which EPA tracks incident data for pesticide products.

3. **California toxicologists said the Bayer studies the EPA relied on to approve the collars underestimated the harm to adult dogs and cats. However, the EPA approved them. What science is there to support these registrations? How can customers know that these are safe to use?**

The pesticide product label, which must be followed under federal law, contains directions and any appropriate precautionary language so that there is:

- 1) reasonable certainty of no harm to humans, and
- 2) no unreasonable adverse effects to the environment.

To reach a registration decision and inform the label language, the data that EPA requires includes data on pesticide residues, toxicology, companion animal safety, and efficacy. EPA then independently reviews those data to inform the registration decision. EPA uses this information to determine if and how a product may be used.

4. **There have been at least 907 human-related incidents since 2013, according to EPA data. Is this a high number? Is there any sort of threshold for removing the collar from the market?**

EPA analyzed reports of human-related incident data as part of its registration review of flumethrin and imidacloprid. EPA also conducted a larger epidemiological analysis of human incident data associated with pyrethroids (Pyrethroids: Tier II Epidemiological Report, dated April 30, 2019) and found little substantive evidence to suggest a clear, associative or causal relationship between exposure to pyrethroids and adverse effects. EPA will continue to evaluate incident data in future cycles of registration review. EPA may initiate action at any time to address concerns if unreasonable adverse effects are identified. Such actions can range from mandatory label changes to cancellation of the registration.

5. **It is my understanding that Bayer knew about these incidents for years, prior to selling dog collars to Elanco. Did Bayer make Elanco aware of these issues when selling the product to Elanco?**

EPA does not have information on communications between Bayer and Elanco.

6. **From my understanding talking with former EPA staff, Health Canada denied to approve Seresto because of the incident data. Do you have any response to this?**

EPA meets periodically with staff in Canada's Pest Management Regulatory Agency (PMRA) to share information related to pesticide registration and registration review, including how pesticide incident data are generally reported and categorized. However, EPA does not have information specific to PMRA's regulatory decision regarding Seresto.

Message

From: Dennis, Allison [Dennis.Allison@epa.gov]
Sent: 3/4/2021 12:11:51 AM
To: Messina, Edward [Messina.Edward@epa.gov]
CC: Freedhoff, Michal [Freedhoff.Michal@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Ozmen, Shamus [Ozmen.Shamus@epa.gov]; Siedschlag, Gregory [Siedschlag.Gregory@epa.gov]; Rust, Mary [Rust.Mary@epa.gov]
Subject: Re: For Michal/Ed/Rick Approval; Midwest Center; Seresto Followup; DDL Today

Thanks. Sending this forward .

Sent from my iPhone

On Mar 3, 2021, at 6:21 PM, Messina, Edward <Messina.Edward@epa.gov> wrote:

How about for last sentence:

Ex. 5 Deliberative Process (DP)

Ed

Ed Messina, Esq.
Acting Office Director
Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
p: (703) 347-0209

From: Dennis, Allison <Dennis.Allison@epa.gov>
Sent: Wednesday, March 3, 2021 6:10 PM
To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Rust, Mary <Rust.Mary@epa.gov>
Subject: Re: For Michal/Ed/Rick Approval; Midwest Center; Seresto Followup; DDL Today

Any updates, mike and Ed? OPA is looking to get back to this reporter tonight .

Sent from my iPhone

On Mar 3, 2021, at 4:06 PM, Freedhoff, Michal <Freedhoff.Michal@epa.gov> wrote:

That is fine w me if fine w OPP. What can we say about the incident data that is getting raised in these pieces?

Michal Freedhoff, Ph.D.
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Freedhoff.michal@epa.gov

From: Dennis, Allison <Dennis.Allison@epa.gov>
Sent: Wednesday, March 3, 2021 3:53 PM
To: Messina, Edward <Messina.Edward@epa.gov>; Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Rust, Mary <Rust.Mary@epa.gov>
Subject: RE: For Michal/Ed/Rick Approval; Midwest Center; Seresto Followup; DDL Today

Good call. Send updated statement below in highlights for approval.

FYI: We are getting more press inquiries on this matter which we responding to with our general statement developed yesterday. We are also getting citizen inquires through the regions, NPIC, and our pesticidequestions@epa.gov.

From: Messina, Edward <Messina.Edward@epa.gov>
Sent: Wednesday, March 3, 2021 3:32 PM
To: Dennis, Allison <Dennis.Allison@epa.gov>; Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Rust, Mary <Rust.Mary@epa.gov>
Subject: RE: For Michal/Ed/Rick Approval; Midwest Center; Seresto Followup; DDL Today

Ex. 5 Deliberative Process (DP)

Ed Messina, Esq.
Acting Office Director
Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
p: (703) 347-0209

From: Dennis, Allison <Dennis.Allison@epa.gov>
Sent: Wednesday, March 3, 2021 3:30 PM
To: Messina, Edward <Messina.Edward@epa.gov>; Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siedschlag, Gregory

<Siedschlag.Gregory@epa.gov>

Subject: For Michal/Ed/Rick Approval; Midwest Center; Seresto Followup; DDL Today

Importance: High

All, How's this as a response back to the Midwest Center? He asked:

1. I was wondering what that means about the Biden-Harris administration taking pet health seriously. Is the agency planning to take action on Seresto?
2. Also, in the statement, the agency says people should follow the label. Is there a problem with people not following the label in these incidents?

Statement:

Ex. 5 Deliberative Process (DP)

From: Johnathan Hettinger <jhettinger@investigatemitwest.org>

Sent: Wednesday, March 3, 2021 11:28 AM

To: Daguillard, Robert <Daguillard.Robert@epa.gov>

Cc: Labbe, Ken <Labbe.Ken@epa.gov>; Press <Press@epa.gov>

Subject: Re: Seresto - Midwest Center for Investigative Reporting

Robert,

I wanted to follow-up on my Seresto story. I saw the statement that the agency provided to the New York Post. <https://t.co/DnvhOr34Fk?amp=1>

I was wondering what that means about the Biden-Harris administration taking pet health seriously. Is the agency planning to take action on Seresto?

Also, in the statement, the agency says people should follow the label. Is there a problem with people not following the label in these incidents?

Thanks,
Johnathan

From: Daguiard, Robert <Daguiard.Robert@epa.gov>
Sent: Friday, February 12, 2021 8:42 AM
To: Johnathan Hettinger
<jhettinger@investigatemidwest.org>; Labbe, Ken
<Labbe.Ken@epa.gov>
Cc: Press <Press@epa.gov>
Subject: RE: Seresto - Midwest Center for Investigative Reporting

Good morning Jonathan,

For attribution to “an EPA Spokesperson,” please:

- 1. According to a records request of EPA documents, there have been at least 75,000 incident reports involving pets, including 1,698 deaths. Is this a high number? Why is it still sold? Is there any sort of threshold for removing the collar from the market?**
- 2. California toxicologists said the Bayer studies the EPA relied on to approve the collars underestimated the harm to adult dogs and cats. However, the EPA approved them. What science is there to support these registrations? How can customers know that these are safe to use?**

Combined Response to the above questions:

The active ingredients in the Seresto collar are flumethrin and imidacloprid. Both have undergone registration review (examination of active ingredients every 15 years to make sure they continue to meet the FIFRA standard for registration), On the basis of current information, both have been found eligible for continued registration. During the registration and registration review processes, the Agency uses the best available science to reach its decision. This includes articles in peer-reviewed journals in addition to the studies submitted by the registrant.

EPA takes every incident reported seriously. If any pesticide is found to present unreasonable adverse effects on the environment as defined in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), or is found not to be safe under the Federal Food, Drug and Cosmetic Act, the Agency would take

appropriate regulatory action. Any such action would, again, need to be supported by the best-available, peer-reviewed science. Regulatory action might include anything from changing the label instructions for use to cancelling the registration.

On the Registration process: Under FIFRA, EPA must make a determination that the product will not cause “unreasonable adverse effects on the environment,” defined in FIFRA 2(bb) as (in part) “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.” Thus, the benefits of a product must be weighed against the risks.

To reach a registration decision and inform the label language, the data that EPA requires includes data on pesticide residues, toxicology, companion animal safety, and efficacy. EPA then independently reviews those data to inform the registration decision. EPA uses this information to determine if and how a product may be used. Evaluations for pet products like shampoos, collars and spot-ons rely upon data on companion animal safety, efficacy and safety for humans who may be exposed as a result of product use.

No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk. The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.

3. It is my understanding that these incidents do not include the main incident reporting system, which likely has additional incidents. Do you have more information about the number of incidents?

Manufacturers are required under law to report adverse incident information to EPA. Individuals may report incidents potentially associated with use of an EPA-registered product by contacting the product manufacturer, their state lead pesticide agency, the National Pesticide Information Center, or by contacting EPA directly through its Incident Data System.

4. **There have been at least 907 human-related incidents since 2013, according to EPA data. Is this a high number? Is there any sort of threshold for removing the collar from the market?**

As stated in the Flumethrin: Tier I Update Review of Human Incidents and Epidemiology for Proposed Interim Decision, dated Sept. 17, 2019, there was a total of 626 incidents in EPA's Main and Aggregate IDSs. While some major incidents were reported (including dermal and neurological symptoms), the vast majority of the incidents were classified as moderate or lower in severity.

EPA also conducted a larger epidemiological analysis of human incident data associated with pyrethroids (Pyrethroids: Tier II Epidemiological Report, dated April 30, 2019) and found little substantive evidence to suggest a clear, associative or causal relationship between exposure to pyrethroids and adverse effects. EPA will continue to evaluate incident data in future cycles of registration review. EPA may initiate action at any time to address concerns if unreasonable adverse effects are identified. Such actions can range from mandatory label changes to cancellation of the registration.

5. **It is my understanding that Bayer knew about these incidents for years, prior to selling dog collars to Elanco. Did Bayer make Elanco aware of these issues when selling the product to Elanco?**

EPA does not have information on communications between Bayer and Elanco.

6. **From my understanding talking with former EPA staff, Health Canada denied to approve Seresto because of the incident data. Do you have any response to this?**

EPA cannot speak to Health Canada's decisionmaking process related to the Seresto collar. While the Seresto collar is not registered in Canada, it is registered in most countries in the European Union and Australia.

Best, R.

Robert Daguiard
Public Affairs Officer
U.S. Environmental Protection
Agency
Washington, DC
+1 (202) 564-6618 (o)
Ex. 6 Personal Privacy (PP)

From: Johnathan Hettinger
<jhettinger@investigatemidwest.org>
Sent: Tuesday, February 09, 2021 11:43 AM
To: Labbe, Ken <Labbe.Ken@epa.gov>
Cc: Press <Press@epa.gov>
Subject: Re: Seresto - Midwest Center for Investigative
Reporting

Ken,

I wanted to circle back. USA Today Network is
republishing this, and my editors there are really
wanting me to get a response from the EPA. They also
want me to reach out to senators/house members on
the issue, so I'll be doing that.

One question they wanted me to make sure I ask: Is
there any way to compare the complaints/incidents for
Seresto versus other common flea collars?

Thanks,
Johnathan

On Tue, Feb 2, 2021 at 8:11 AM Labbe, Ken
<Labbe.Ken@epa.gov> wrote:

Hi Johnathan,

Still working to be responsive on this for you. We
appreciate your continued patience. Will circle back
with you when I have something.

Thanks,

Ken

From: Johnathan Hettinger
<jhettinger@investigatemidwest.org>
Sent: Tuesday, February 2, 2021 10:08 AM
To: Labbe, Ken <Labbe.Ken@epa.gov>
Cc: Press <Press@epa.gov>
Subject: Re: Seresto - Midwest Center for Investigative Reporting

Just wanted to follow-up on this. Thanks!

On Fri, Jan 29, 2021 at 9:54 AM Labbe, Ken
<Labbe.Ken@epa.gov> wrote:

We appreciate your flexibility, Johnathan. Thank you.

From: Johnathan Hettinger
<jhettinger@investigatemidwest.org>
Sent: Friday, January 29, 2021 10:58 AM
To: Labbe, Ken <Labbe.Ken@epa.gov>
Cc: Press <Press@epa.gov>
Subject: Re: Seresto - Midwest Center for Investigative Reporting

Yes, we can wait until COB Monday. That is fine.
Thank you.

On Jan 29, 2021, at 7:34 AM, Labbe,
Ken <Labbe.Ken@epa.gov> wrote:

Hi Johnathan,

We're working on being responsive to your inquiry, however will require more time. Can you extend your deadline? COB Monday perhaps? If you cannot extend, will you update with our response once it's received?

-Ken

From: Johnathan Hettinger
<jhettinger@investigatemidwest.org>
Sent: Thursday, January 28, 2021 3:32 PM
To: Labbe, Ken
<Labbe.Ken@epa.gov>
Cc: Press <Press@epa.gov>
Subject: Re: Seresto - Midwest Center for Investigative Reporting

Ken,

For those numbers, I'm citing the attached document on aggregate incidents. But if you look at the human incident report in the other document, there is an aggregate IDS and a main IDS. From my understanding, the aggregate is not all of the incidents.

Does that make sense? You can give me a call at 217-493-9791 if that helps.

Thanks,

Johnathan

On Thu, Jan 28, 2021 at 12:14 PM
Labbe, Ken <Labbe.Ken@epa.gov>
wrote:

Hi Johnathan,

I'd like some clarification on what you mean by, "It is my understanding that these incidents do not include the main incident reporting system, which likely has additional incidents."

More information on this would help us be responsive to your inquiry. Please advise.

Thanks,

Ken

From: Johnathan Hettinger
<jhettinger@investigatemitwest.org>
>
Sent: Tuesday, January 26, 2021
4:05 PM
To: Press <Press@epa.gov>;
Daguillard, Robert
<Daguillard.Robert@epa.gov>;
Labbe, Ken <Labbe.Ken@epa.gov>;
Jones, Enesta
<Jones.Enesta@epa.gov>
Subject: Seresto - Midwest Center
for Investigative Reporting

Hello,

I'm a reporter with the Midwest Center for Investigative Reporting, a nonprofit newsroom based in Champaign, Illinois, that covers agribusiness. I am working on a story about EPA incident data surrounding Seresto collars. It is my understanding

that there have been a significant amount of incidents surrounding the pesticides in the collars, and I had some questions.

According to a records request of EPA documents, there have been at least 75,000 incident reports involving pets, including 1,698 deaths. Is this a high number? Why is it still sold? Is there any sort of threshold for removing the collar from the market?

It is my understanding that these incidents do not include the main incident reporting system, which likely has additional incidents. Do you have more information about the number of incidents?

California toxicologists said the Bayer studies the EPA relied on to approve the collars underestimated the harm to adult dogs and cats. However, the EPA approved them. What science is there to support these registrations? How can customers know that these are safe to use?

There have been at least 907 human-related incidents since 2013, according to EPA data. Is this a high number? Is there any sort of threshold for removing the collar from the market?

It is my understanding that Bayer knew about these incidents for years, prior to selling dog collars to Elanco. Did Bayer make Elanco aware of these

issues when selling the product
to Elanco?

From my understanding talking
with former EPA staff, Health
Canada denied to approve
Seresto because of the incident
data. Do you have any response
to this?

If possible, I would very much like
to speak to someone for this
story. Please let me know if you
would have some time. My
deadline is Friday, end-of-day.

Thanks,

Johnathan Hettinger

Investigative Reporter

Midwest Center for Investigative
Reporting

217-493-9791

Message

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 6/18/2020 12:34:20 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Saunders, Jennifer [Saunders.Jennifer@epa.gov]
Subject: Fwd: Contact the EPA about Pets

FYI. Last year, the team was exploring with OGC if we could
Ex. 5 AC/DP Might be something to consider following up on.

Ex. 5 AC/DP

Best,
Catherine
Associate Director (Acting)
OPP Registration Division
US Environmental Protection Agency

Begin forwarded message:

From: Aubee.Catherine@epa.gov
Date: June 18, 2020 at 8:29:58 AM EDT
To: "Ingram, Earl" <Ingram.Earl@epa.gov>
Cc: "Miller, Robert" <Miller.Robert@epa.gov>, "Smith, Kimberly" <Smith.Kimberly@epa.gov>, "Motilall, Christina" <Motilall.Christina@epa.gov>, Charles Smith <Smith.Charles@epa.gov>
Subject: Re: Contact the EPA about Pets

Thanks for looping us in. Looping in PRD.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Best,
Catherine
Associate Director (Acting)
OPP Registration Division
US Environmental Protection Agency

On Jun 18, 2020, at 8:26 AM, Ingram, Earl <Ingram.Earl@epa.gov> wrote:

Hello Bob,

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Let me know if you have any questions.

I hope all is well with you and your love ones.

Earl Ingram, Chief
Public Information & Records Integrity Branch
Information Technology & Resources Management Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 305-5456

From: Miller, Robert <Miller.Robert@epa.gov>
Sent: Thursday, June 18, 2020 6:57 AM
To: Ingram, Earl <Ingram.Earl@epa.gov>
Cc: Smith, Kimberly <Smith.Kimberly@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>
Subject: FW: Contact the EPA about Pets

Hi Earl,

Hope you and your family are doing well. A member of the public is asking about Seresto incident reporting. She likely needs to go through the FOIA process, but asking one person to go through the process seems like a bit much.

Bob

Robert A. Miller
6(a)(2) Coordinator
Information Technology and Resource Management Division
EPA Office of Pesticide Programs
Mail Code 7508P
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W., Washington D.C.

(703) 347-8012
miller.robert@epa.gov

From: Sharpe, Kristinn <Sharpe.Kristinn@epa.gov>
Sent: Wednesday, June 17, 2020 5:05 PM
To: Miller, Robert <Miller.Robert@epa.gov>
Subject: FW: Contact the EPA about Pets

Hi Robert,

Please see the below email that came in through the web portal.

Thank you,
Kristinn

From: pesticidequestions

Sent: Wednesday, June 17, 2020 4:48 PM

To: Ex. 6 PP – personal name Ex. 6 PP – personal email

Subject: RE: Contact the EPA about Pets

Dear Ex. 6 PP – personal name

Thank you for writing the Environmental Protection Agency's pesticides program.

We are sorry to hear about your pet. We understand this is a stressful time.

We will forward the information you provided to our adverse effects reporting branch. Please be sure to provide the same information you provided to us to your veterinarian to ensure the best diagnosis and follow-up care. You might also want to contact the National Pesticide Information Center, an EPA information-sharing partner that has staff who are specially trained in responding to pesticide exposure incidents, including those involving pets.

We hope you find this information useful. Please write us again if you have additional questions.

Best regards,
Office of Pesticide Programs
U.S. Environmental Protection Agency

-----Original Message-----

From: drupal_admin@epa.gov <drupal_admin@epa.gov> On Behalf Of Ex. 6 PP – personal name

Ex. 6 PP – personal name via EPA

Sent: Thursday, May 14, 2020 1:40 PM

To: pesticidequestions <pesticidequestions@epa.gov>

Subject: Contact the EPA about Pets

Submitted on 05/14/2020 1:40PM

Submitted values are:

Name: Ex. 6 PP – personal name

E-mail: Ex. 6 PP – personal email

Comments:

I came across this pdf file about Seresto flea collars. As you will see below the link I included a statement in the pdf file. Stating EPA has received reports of undesirable effects to domestic animals using Seresto. I am researching because we decided to try that out late last year and our dog wore it till Jan 2020. Now we have notice lymph node issues as we are next scheduled for a biopsy and hoping it isn't cancer. I have owned many of dogs and usually I use advantage instead of a flea collar. Now I wonder as this all started to happen we first decided to go with a flea collar that was really expensive but has so many chemicals as you even have to be careful around kids. Which

doesn't make sense how it doesn't hard animals. I am inquiring about the incident reporting information to see what data of complaints have been reported. Thank you!

https://www.epa.gov/sites/production/files/2017-01/documents/weighing_risks_to_children_from_dogs_wearing_seresto-tm_collars.pdf

Since the initial registration, EPA has received reports of undesirable effects to domestic animals using Seresto™ collars. EPA is evaluating those reports as part of the current registration review of flumethrin.

Message

From: Keigwin, Richard [Keigwin.Richard@epa.gov]
Sent: 3/3/2021 2:01:58 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]
Subject: Re: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar

Sorry I wasn't able to get to the General yesterday. Was in a summit with ORD.

Rick Keigwin
Acting Deputy Assistant Administrator for Management
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Phone: 202-564-2910
Sent from my iPhone (Please excuse typos!)

On Mar 3, 2021, at 8:58 AM, Goodis, Michael <Goodis.Michael@epa.gov> wrote:

Yep – brought it up during the OPP general. Michal OK with the FR going out as is.
Comms to make sure they have a desk statement prepared that will also address potential criticism if it comes up.
Thanks for checking.

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
571-309-5497 (cell)

From: Keigwin, Richard <Keigwin.Richard@epa.gov>
Sent: Wednesday, March 03, 2021 8:56 AM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar

Did Ed get back to you on this?

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Tuesday, March 02, 2021 2:19 PM
To: Dennis, Allison <Dennis.Allison@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
571-309-5497 (cell)

From: Dennis, Allison <Dennis.Allison@epa.gov>

Sent: Tuesday, March 02, 2021 10:53 AM

To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>

Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>;

Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>;

Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>

Subject: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Head's up on this story. We're working up a statement regarding our incident data to use if needed. - Allison

https://apple.news/A78_uo4GiQWg_FP9GTVxg9w

Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Johnathan Hettinger

Midwest Center for Investigative Reporting

Rhonda Bomwell had never used a flea and tick collar before. Pierre, her 9-year-old Papillon service dog, was mostly an indoor animal.

Still, her veterinarian recommended she purchase one, so Bomwell went to the pet store near her home in Somerset, New Jersey, and selected Bayer's Seresto collar.

A day later, on June 2, 2020, Pierre had a seizure, collapsing while Bomwell was making dinner. Lying on his back, the dog stopped breathing and his eyes rolled back.

Bomwell tried giving him CPR. Then she called the police. An officer helped her lift the dog into her car, and she rushed him to the hospital. Pierre died before he could receive medical treatment. Bomwell didn't think to take off Pierre's collar.

"I just didn't put it together," she said.

Bomwell isn't alone. Seresto, one of the most popular flea and tick collars in the country, has been linked to hundreds of pet deaths, tens of thousands of injured animals and hundreds of harmed humans, U.S. Environmental Protection Agency documents show.

Yet the EPA has done nothing to inform the public of the risks.

Seresto, developed by Bayer and now sold by Elanco, works by releasing small amounts of pesticide onto the animal for months at a time. The pesticide is supposed to kill fleas, ticks and other pests but be safe for cats and dogs.

<image001.jpg>

But thousands of pets are being harmed, according to federal documents obtained through a public records request from the Center for Biological Diversity, a nonprofit organization that watchdogs the EPA as part of its work to protect endangered species. The center provided the documents to the Midwest Center for Investigative Reporting.

Since Seresto flea and tick collars were introduced in 2012, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, including nearly 1,000 involving human harm.

The EPA is in charge of regulating products that contain pesticides. The agency has known about these incidents for years but has not informed the public of the potential risks associated with this product, said Karen McCormack, a retired EPA employee who worked as both a scientist and communications officer.

McCormack said the collars have the most incidents of any pesticide pet product she's ever seen.

"The EPA appears to be turning a blind eye to this problem, and after seven years of an increasing number of incidents, they are telling the public that they are continuing to monitor the situation," she said. "But I think this is a significant problem that needs to be addressed sooner rather than later."

<image002.jpg>

The EPA declined to say how Seresto compares to other pet products. But in response to a question about whether the product is safe, an agency spokesperson said in an

emailed statement that the two pesticides in Seresto have “been found eligible for continued registration” based on best available science, including incident data.

“No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk,” the spokesperson said. “The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.”

Amazon, where Seresto is the top-selling collar, also has received numerous complaints about the product from customers who detailed significant issues. Dozens of people over the years have claimed the collar caused skin rashes in their pet. Others said it led to neurological issues in their pets.

Despite the many warnings, Amazon has not removed the product from its online marketplace. Amazon did not respond to multiple requests for comment for this story.

This isn’t the first time that the EPA has failed to properly regulate flea and tick collars containing pesticides, said Miriam Rotkin-Ellman, a senior scientist at the Natural Resources Defense Council.

The NRDC filed a petition against the agency more than a decade ago over its approval of a different pesticide than the one used in Seresto that is linked to cancer and brain development issues in children.

In April 2020, a federal appeals court called the EPA’s refusal to respond to NRDC’s requests “nothing short of egregious” and told agency officials to make a decision on whether to ban the pesticide within 90 days. The EPA decided not to ban the pesticide, called tetrachlorvinphos. That pet collar continues to be sold under the brand name Hartz Ultraguard, Hartz InControl and Longlife.

NRDC has challenged that decision; that lawsuit is currently pending.

Even so, the number of incidents linked to that pesticide pales in comparison to those linked to Seresto. From 1992 to 2008, the EPA received about 4,600 incident reports regarding pet collars containing tetrachlorvinphos, including 363 deaths, according to EPA documents.

Broken down per year, that's 30 times fewer incidents and 10 times fewer deaths than Seresto.

And those are most likely an undercount, said Nathan Donley, a senior scientist at the Center for Biological Diversity and an expert on U.S. pesticide regulation. Donley said the number of reported incidents for Seresto is "just the tip of the iceberg."

In order to report an incident, a person has to make the connection between the collar and the issue with the dog, understand who to contact and how to report it, he said.

"Most of the time, people are not going to make the connection or they're not going to take an hour or so out of the day and figure out how to call and spend time on hold," Donley said.

He said the incident data creates lots of questions about EPA processes.

"My God, if this doesn't trigger a concern, that's a fundamental problem with the process," Donley said. "The fact that EPA has not done anything to alert the public that there might be an issue here, it strikes me as bordering on criminal. The EPA has this system in place to compile information and it's just collecting dust in some database."

A big business

Pet collars are big business. In its 2019 annual report, German agribusiness and pharmaceutical company Bayer reported revenue of more than \$300 million on Seresto alone.

The company sold its animal health division to Elanco Animal Health, a former subsidiary of Eli Lilly and Co., for \$7.6 billion in 2019. The deal was finalized in 2020. As part of the deal, Bayer received \$2.3 billion in Elanco stock, which the company said it would sell over time.

Bayer did not respond to multiple requests for comment.

Since being spun off as its own company in 2019, Elanco has lobbied the EPA quarterly on issues relating to animal health, according to the the nonprofit Center for Responsive Politics, which maintains a website tracking political contributions. Over two years, the company has spent \$1.6 million on lobbying, records show.

Keri McGrath, a spokeswoman for Elanco, said in an email the company “takes the safety of our products very seriously and thoroughly investigates potential concerns related to their use.” McGrath pointed out that regulatory authorities have approved the product in more than 80 countries, and the EPA is in the final stages of re-approving both pesticides. There is no timeline on the final decision.

McGrath said that global data shows that 1 in 568 users of Seresto have an incident and “the majority of these incident reports relate to non-serious effects such as application site disorders, e.g. a reddening of the skin or hair loss below the collar.”

“Keep in mind that the existence of an adverse event report does not necessarily mean the product caused the problem,” she said. “Causality between the observed signs and the use of the product is evaluated on a case-by-case basis. That said, every adverse event collected, regardless of causality, is reported to the authorities.”

<image003.jpg>

The EPA did not respond to a request about how Seresto compared to other flea and tick collars in terms of incidents. The Midwest Center has filed a Freedom of Information request for the incident database, but that request has not yet been filled.

The extent of the damage is uncommon, said McCormack, the former EPA staffer.

“I’ve never seen any product that had 75,000 incidents,” McCormack said.

Seresto’s pesticides more toxic together

The EPA approved Seresto collars on March 16, 2012. The collars are designed to work for eight months.

Under the Federal Insecticide, Fungicide and Rodenticide Act, the EPA must determine a pesticide product will not cause “unreasonable effects on the environment.”

This determination requires weighing harms versus benefits, including assessments of risks to human health and the environment.

Seresto contains two pesticides: imidacloprid and flumethrin.

Imidacloprid belongs to the neonicotinoid class of insecticides, which are the most commonly used insecticides on crops in the U.S. Despite neonicotinoids being connected to massive die-offs of non-target insects such as bees and butterflies, the EPA proposed re-approving imidacloprid and other class members last year. The pesticide is banned in the European Union for outdoor use but allowed in pet collars. There is also growing evidence that mammals can be harmed by these pesticides as well.

Flumethrin, EPA documents show, is only an active ingredient in one product: Seresto.

Like with most pesticides, the data supporting the registration of Seresto was conducted by the company that produced it, Bayer. The majority of the studies were looking at each pesticide individually.

However, a 2012 Bayer study found they have a “synergistic effect,” meaning they are more toxic together on fleas. The study found that the “unique pharmacological synergism” works as quickly as six hours to prevent ticks from attaching and feeding, preventing disease transmission.

Additionally, eight companion animal safety studies were conducted by Bayer looking at the effect of Seresto collars on domestic cats and dogs. The EPA used these studies to approve Seresto. The California Department of Pesticide Regulation took issue with the validity of two of the studies but approved the collars anyway.

Another issue could be a reaction of inactive ingredients, which are unknown and have caused problems in spot-on treatments, said Donley of the Center for Biological Diversity.

Donley, who has a doctorate in cell and developmental biology and is a former cancer researcher, said this “synergistic effect” likely extends to pets. He said he wasn’t sure what makes the two pesticides so likely to cause harm, but it is clear something is wrong with the product.

“You don’t even see these kinds of numbers with many agricultural chemicals,” Donley said.

“For whatever reason, this combination is just really nasty.”

History of unsafe pet treatments

There are currently 18 flea and tick collars on the market: three that are approved for both dogs and cats (including Seresto), 10 approved for dogs and five for cats, according to the National Pesticide Information Center.

In addition to allowing tetrachlorvinphos in pet collars despite evidence of its unsafety, the EPA also had approved the use of another pesticide linked to cancer and brain development problems – propoxur, which was sold under many brand names, including Bio Spot, Scratex Color, Zodiac, Sergeant's Dual Action and Sentry Dual Action.

Rotkin-Ellman's research showed residues were high enough to pose a risk to children and adults who play with pets that were wearing the collars.

In April 2016, pesticide companies voluntarily agreed to stop using propoxur to help protect children's health. The brand names that used propoxur have switched to other active ingredients.

In addition, in 2010, the EPA increased label requirements and limited some inert ingredients in spot-on treatments, which are applied to a specific area of a pet. This happened after incident data showed the treatments were causing hundreds of pet deaths, as well as issues such as irritation, rashes and hair loss, gastrointestinal problems and seizures.

Collars have caused seizures, rashes in humans

It's not just pets that are being harmed, EPA documents show.

Between 2013 and 2018, 907 incidents were reported with humans, according to a September 2019 EPA assessment of human health risk.

The assessment determined that there were 19 severe incidents. Of those, eight people had dermal symptoms, such as a rash or hives, and seven had neurological symptoms, which included numbness and headaches.

Incidents listed by the EPA included:

- A 12-year-old boy who slept in a bed with a dog wearing a collar started having seizures and vomiting. He had to be hospitalized.
- A 67-year-old woman who slept in a bed with a dog wearing a collar reported having heart arrhythmia and fatigue.
- A 43-year-old man put collars on eight dogs and slept in the same bed as four of the dogs. A week later, he developed ear drainage and nasal and throat irritation and was told by a doctor that he had a hole in his ear drum. He removed the dog collars and the symptoms went away. He later reapplied the collars and the symptoms returned.

An October 2016 EPA bulletin responded to citizen concerns about children being exposed to Seresto, saying it had found exposure to the collars to be negligible.

“As stated in the precautions on the label, do not allow children to play with the collars. In addition, try to keep the pet away from young children for a day after putting on the collar to minimize exposure,” the bulletin said.

“It’s really not just happening to animals. It’s happening to people who pet them as well,” Donley said. “I have two young kids who are all over our dog all the time. I can imagine how highly exposed people would be to residues.”

‘It’s just been a nightmare’

To Bomwell, the worst part was the lack of warning. Pierre had never been sick or had a seizure. He was just 9, so she thought he had half a decade left. Her last dog had died at 18. Plus, she felt like she was responsible. She was the one who put the collar on.

“It was so bizarre,” Bomwell said. “It’s just been a nightmare.”

Even if the EPA had not received tens of thousands of complaints, a cursory search of the web would find dozens of posts from pet owners warning others to be careful with the collars, including a letter to an animal doctor column in the St. Louis Post-Dispatch in 2013, a radio news story in New York in 2016 and extensive comments on pet forums.

Without the federal government stepping in, individuals are left in the dark. That’s something Ron Packard, of Brockton, Massachusetts, is hoping to address.

In the days after the death of his two dogs in June 2019, Packard did what any person looking for answers does: He went to the internet.

Two of Packard's four dogs had recently had seizures on the same day, before becoming lethargic and vomiting and finally, refusing to eat. He brought them to the veterinarian, who couldn't find a problem.

Within weeks, the two previously healthy cavachons, 10-year-old Danny and 5-year-old Dominic, were both dead.

<image004.jpg>

The only thing Packard could figure out was both dogs had started wearing Seresto flea and tick collars a month before.

"Thirty-three and 54 days later, they're both dead," Packard said.

Packard created a Facebook page, asking people who had similar issues to share their stories.

Today, the page fills up with pictures and stories like Packard's.

A dog starts wearing a collar. Within weeks, a dog will have a seizure, sometimes it will later die. Other stories aren't quite as extreme. Loss of hair around the neck. Lethargy.

Packard encourages everyone to report their story to the EPA.

"I don't want others to go through what we went through," he said. "Every time I read the stories, it brings me back to my dogs. But if I can save a few pets, I can deal with it."

This story is a collaboration between USA TODAY and the Midwest Center for Investigative Reporting. The center is an independent, nonprofit newsroom covering agribusiness, Big Ag and related issues. USA TODAY is funding a fellowship at the center for expanded coverage of agribusiness and its impact on communities.

Message

From: Freedhoff, Michal [Freedhoff.Michal@epa.gov]
Sent: 3/2/2021 10:22:26 PM
To: Dennis, Allison [Dennis.Allison@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]
CC: Messina, Edward [Messina.Edward@epa.gov]; Siedschlag, Gregory [Siedschlag.Gregory@epa.gov]; Ozmen, Shamus [Ozmen.Shamus@epa.gov]; Siciliano, CarolAnn [Siciliano.CarolAnn@epa.gov]
Subject: RE: 3/2 USA Today/Midwest Center; Pet Collars; 5 pm DDL hard

sure

Michal Freedhoff, Ph.D.
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Freedhoff.michal@epa.gov

From: Dennis, Allison <Dennis.Allison@epa.gov>
Sent: Tuesday, March 2, 2021 5:22 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>; Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center; Pet Collars; 5 pm DDL hard

This works for me.

Michal-?

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Tuesday, March 2, 2021 5:06 PM
To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center; Pet Collars; 5 pm DDL hard

Propose the following edits – **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
571-309-5497 (cell)

From: Freedhoff, Michal <Freedhoff.Michal@epa.gov>
Sent: Tuesday, March 02, 2021 4:54 PM
To: Dennis, Allison <Dennis.Allison@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center; Pet Collars; 5 pm DDL hard

Ok – and I also defer to Ed/Mike

Michal Freedhoff, Ph.D.
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Freedhoff.michal@epa.gov

From: Dennis, Allison <Dennis.Allison@epa.gov>
Sent: Tuesday, March 2, 2021 4:53 PM
To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center; Pet Collars; 5 pm DDL hard

Re: pets. How about this instead: Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

I defer to Ed/Mike on the data comment.

From: Freedhoff, Michal <Freedhoff.Michal@epa.gov>
Sent: Tuesday, March 2, 2021 4:38 PM
To: Dennis, Allison <Dennis.Allison@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center; Pet Collars; 5 pm DDL hard

Ex. 5 Deliberative Process (DP)

Michal Freedhoff, Ph.D.
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Freedhoff.michal@epa.gov

From: Dennis, Allison <Dennis.Allison@epa.gov>
Sent: Tuesday, March 2, 2021 4:31 PM
To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>

Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>

Subject: RE: 3/2 USA Today/Midwest Center; Pet Collars; 5 pm DDL hard

We've had multiple asks for comment on this story. Here's what we would like to run by OPA (Lindsey/Nick) with your approval (see below). Note the "statement" part is the "quotable" part of our responses whereas as the "background" portion is what a reporter can use on background. **Ed/Mike**, I don't know if we can go as far as the highlighted part but I do want to say something about the incident data. -Allison

Ex. 5 Deliberative Process (DP)

From: Freedhoff, Michal <Freedhoff.Michal@epa.gov>

Sent: Tuesday, March 2, 2021 12:39 PM

To: Dennis, Allison <Dennis.Allison@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>

Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>

Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Thanks – I'd be interested in what our incident data shows. There have been a number of pet product questions that have come up since I started. Let's discuss whether there is more we could/should be doing at our next OPP general.

Michal Freedhoff, Ph.D.

Acting Assistant Administrator

Office of Chemical Safety and Pollution Prevention

From: Dennis, Allison <Dennis.Allison@epa.gov>

Sent: Tuesday, March 2, 2021 10:53 AM

To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>

Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>

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https://apple.news/A78_uo4GiQWq_FP9GTVxg9w

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Johnathan Hettinger

Midwest Center for Investigative Reporting

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"I just didn't put it together," she said.

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Yet the EPA has done nothing to inform the public of the risks.

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The EPA declined to say how Seresto compares to other pet products. But in response to a question about whether the product is safe, an agency spokesperson said in an emailed statement that the two pesticides in Seresto have “been found eligible for continued registration” based on best available science, including incident data.

“No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk,” the spokesperson said. “The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.”

Amazon, where Seresto is the top-selling collar, also has received numerous complaints about the product from customers who detailed significant issues. Dozens of people over the years have claimed the collar caused skin rashes in their pet. Others said it led to neurological issues in their pets.

Despite the many warnings, Amazon has not removed the product from its online marketplace. Amazon did not respond to multiple requests for comment for this story.

This isn't the first time that the EPA has failed to properly regulate flea and tick collars containing pesticides, said Miriam Rotkin-Ellman, a senior scientist at the Natural Resources Defense Council.

The NRDC filed a petition against the agency more than a decade ago over its approval of a different pesticide than the one used in Seresto that is linked to cancer and brain development issues in children.

In April 2020, a federal appeals court called the EPA's refusal to respond to NRDC's requests "nothing short of egregious" and told agency officials to make a decision on whether to ban the pesticide within 90 days. The EPA decided not to ban the pesticide, called tetrachlorvinphos. That pet collar continues to be sold under the brand name Hartz Ultraguard, Hartz InControl and Longlife.

NRDC has challenged that decision; that lawsuit is currently pending.

Even so, the number of incidents linked to that pesticide pales in comparison to those linked to Seresto. From 1992 to 2008, the EPA received about 4,600 incident reports regarding pet collars containing tetrachlorvinphos, including 363 deaths, according to EPA documents.

Broken down per year, that's 30 times fewer incidents and 10 times fewer deaths than Seresto.

And those are most likely an undercount, said Nathan Donley, a senior scientist at the Center for Biological Diversity and an expert on U.S. pesticide regulation. Donley said the number of reported incidents for Seresto is "just the tip of the iceberg."

In order to report an incident, a person has to make the connection between the collar and the issue with the dog, understand who to contact and how to report it, he said.

"Most of the time, people are not going to make the connection or they're not going to take an hour or so out of the day and figure out how to call and spend time on hold," Donley said.

He said the incident data creates lots of questions about EPA processes.

"My God, if this doesn't trigger a concern, that's a fundamental problem with the process," Donley said. "The fact that EPA has not done anything to alert the public that there might be an issue here, it strikes me as bordering on criminal. The EPA has this system in place to compile information and it's just collecting dust in some database."

A big business

Pet collars are big business. In its 2019 annual report, German agribusiness and pharmaceutical company Bayer reported revenue of more than \$300 million on Seresto alone.

The company sold its animal health division to Elanco Animal Health, a former subsidiary of Eli Lilly and Co., for \$7.6 billion in 2019. The deal was finalized in 2020. As part of the deal, Bayer received \$2.3 billion in Elanco stock, which the company said it would sell over time.

Bayer did not respond to multiple requests for comment.

Since being spun off as its own company in 2019, Elanco has lobbied the EPA quarterly on issues relating to animal health, according to the the nonprofit Center for Responsive Politics, which maintains a website tracking political contributions. Over two years, the company has spent \$1.6 million on lobbying, records show.

Keri McGrath, a spokeswoman for Elanco, said in an email the company “takes the safety of our products very seriously and thoroughly investigates potential concerns related to their use.” McGrath pointed out that regulatory authorities have approved the product in more than 80 countries, and the EPA is in the final stages of re-approving both pesticides. There is no timeline on the final decision.

McGrath said that global data shows that 1 in 568 users of Seresto have an incident and “the majority of these incident reports relate to non-serious effects such as application site disorders, e.g. a reddening of the skin or hair loss below the collar.”

“Keep in mind that the existence of an adverse event report does not necessarily mean the product caused the problem,” she said. “Causality between the observed signs and the use of the product is evaluated on a case-by-case basis. That said, every adverse event collected, regardless of causality, is reported to the authorities.”



The EPA did not respond to a request about how Seresto compared to other flea and tick collars in terms of incidents. The Midwest Center has filed a Freedom of Information request for the incident database, but that request has not yet been filled.

The extent of the damage is uncommon, said McCormack, the former EPA staffer.

“I’ve never seen any product that had 75,000 incidents,” McCormack said.

Seresto’s pesticides more toxic together

The EPA approved Seresto collars on March 16, 2012. The collars are designed to work for eight months.

Under the Federal Insecticide, Fungicide and Rodenticide Act, the EPA must determine a pesticide product will not cause “unreasonable effects on the environment.”

This determination requires weighing harms versus benefits, including assessments of risks to human health and the environment.

Seresto contains two pesticides: imidacloprid and flumethrin.

Imidacloprid belongs to the neonicotinoid class of insecticides, which are the most commonly used insecticides on crops in the U.S. Despite neonicotinoids being connected to massive die-offs of non-target insects such as bees and butterflies, the EPA proposed re-approving imidacloprid and

other class members last year. The pesticide is banned in the European Union for outdoor use but allowed in pet collars. There is also growing evidence that mammals can be harmed by these pesticides as well.

Flumethrin, EPA documents show, is only an active ingredient in one product: Seresto.

Like with most pesticides, the data supporting the registration of Seresto was conducted by the company that produced it, Bayer. The majority of the studies were looking at each pesticide individually.

However, a 2012 Bayer study found they have a “synergistic effect,” meaning they are more toxic together on fleas. The study found that the “unique pharmacological synergism” works as quickly as six hours to prevent ticks from attaching and feeding, preventing disease transmission.

Additionally, eight companion animal safety studies were conducted by Bayer looking at the effect of Seresto collars on domestic cats and dogs. The EPA used these studies to approve Seresto. The California Department of Pesticide Regulation took issue with the validity of two of the studies but approved the collars anyway.

Another issue could be a reaction of inactive ingredients, which are unknown and have caused problems in spot-on treatments, said Donley of the Center for Biological Diversity.

Donley, who has a doctorate in cell and developmental biology and is a former cancer researcher, said this “synergistic effect” likely extends to pets. He said he wasn’t sure what makes the two pesticides so likely to cause harm, but it is clear something is wrong with the product.

“You don’t even see these kinds of numbers with many agricultural chemicals,” Donley said.

“For whatever reason, this combination is just really nasty.”

History of unsafe pet treatments

There are currently 18 flea and tick collars on the market: three that are approved for both dogs and cats (including Seresto), 10 approved for dogs and five for cats, according to the National Pesticide Information Center.

In addition to allowing tetrachlorvinphos in pet collars despite evidence of its unsafety, the EPA also had approved the use of another pesticide linked to cancer and brain development problems – propoxur, which was sold under many brand names, including Bio Spot, Scratex Color, Zodiac, Sergeant’s Dual Action and Sentry Dual Action.

Rotkin-Ellman's research showed residues were high enough to pose a risk to children and adults who play with pets that were wearing the collars.

In April 2016, pesticide companies voluntarily agreed to stop using propoxur to help protect children's health. The brand names that used propoxur have switched to other active ingredients.

In addition, in 2010, the EPA increased label requirements and limited some inert ingredients in spot-on treatments, which are applied to a specific area of a pet. This happened after incident data showed the treatments were causing hundreds of pet deaths, as well as issues such as irritation, rashes and hair loss, gastrointestinal problems and seizures.

Collars have caused seizures, rashes in humans

It's not just pets that are being harmed, EPA documents show.

Between 2013 and 2018, 907 incidents were reported with humans, according to a September 2019 EPA assessment of human health risk.

The assessment determined that there were 19 severe incidents. Of those, eight people had dermal symptoms, such as a rash or hives, and seven had neurological symptoms, which included numbness and headaches.

Incidents listed by the EPA included:

- A 12-year-old boy who slept in a bed with a dog wearing a collar started having seizures and vomiting. He had to be hospitalized.
- A 67-year-old woman who slept in a bed with a dog wearing a collar reported having heart arrhythmia and fatigue.
- A 43-year-old man put collars on eight dogs and slept in the same bed as four of the dogs. A week later, he developed ear drainage and nasal and throat irritation and was told by a doctor that he had a hole in his ear drum. He removed the dog collars and the symptoms went away. He later reapplied the collars and the symptoms returned.

An October 2016 EPA bulletin responded to citizen concerns about children being exposed to Seresto, saying it had found exposure to the collars to be negligible.

"As stated in the precautions on the label, do not allow children to play with the collars. In addition, try to keep the pet away from young children for a day after putting on the collar to minimize exposure," the bulletin said.

“It’s really not just happening to animals. It’s happening to people who pet them as well,” Donley said. “I have two young kids who are all over our dog all the time. I can imagine how highly exposed people would be to residues.”

‘It’s just been a nightmare’

To Bomwell, the worst part was the lack of warning. Pierre had never been sick or had a seizure. He was just 9, so she thought he had half a decade left. Her last dog had died at 18. Plus, she felt like she was responsible. She was the one who put the collar on.

“It was so bizarre,” Bomwell said. “It’s just been a nightmare.”

Even if the EPA had not received tens of thousands of complaints, a cursory search of the web would find dozens of posts from pet owners warning others to be careful with the collars, including a letter to an animal doctor column in the St. Louis Post-Dispatch in 2013, a radio news story in New York in 2016 and extensive comments on pet forums.

Without the federal government stepping in, individuals are left in the dark. That’s something Ron Packard, of Brockton, Massachusetts, is hoping to address.

In the days after the death of his two dogs in June 2019, Packard did what any person looking for answers does: He went to the internet.

Two of Packard’s four dogs had recently had seizures on the same day, before becoming lethargic and vomiting and finally, refusing to eat. He brought them to the veterinarian, who couldn’t find a problem.

Within weeks, the two previously healthy cavachons, 10-year-old Danny and 5-year-old Dominic, were both dead.



The only thing Packard could figure out was both dogs had started wearing Seresto flea and tick collars a month before.

“Thirty-three and 54 days later, they're both dead,” Packard said.

Packard created a Facebook page, asking people who had similar issues to share their stories.

Today, the page fills up with pictures and stories like Packard's.

A dog starts wearing a collar. Within weeks, a dog will have a seizure, sometimes it will later die. Other stories aren't quite as extreme. Loss of hair around the neck. Lethargy.

Packard encourages everyone to report their story to the EPA.

“I don't want others to go through what we went through,” he said. “Every time I read the stories, it brings me back to my dogs. But if I can save a few pets, I can deal with it.”

This story is a collaboration between USA TODAY and the Midwest Center for Investigative Reporting. The center is an independent, nonprofit newsroom covering agribusiness, Big Ag and related issues. USA TODAY is funding a fellowship at the center for expanded coverage of agribusiness and its impact on communities.

Message

From: Ozmen, Shamus [Ozmen.Shamus@epa.gov]
Sent: 3/2/2021 9:48:01 PM
To: Messina, Edward [Messina.Edward@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]
Subject: FW: 3/2 USA Today/Midwest Center; Pet Collars; 5 pm DDL hard

Beyond the statement Allison provided below, Dian has been coordinating with the branches for specific answers to the press inquiries in case we need to follow-up.

Ex. 5 Deliberative Process (DP)

From: Freedhoff, Michal <Freedhoff.Michal@epa.gov>
Sent: Tuesday, March 2, 2021 4:38 PM
To: Dennis, Allison <Dennis.Allison@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center; Pet Collars; 5 pm DDL hard

Ex. 5 Deliberative Process (DP)

Michal Freedhoff, Ph.D.
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Freedhoff.michal@epa.gov

From: Dennis, Allison <Dennis.Allison@epa.gov>
Sent: Tuesday, March 2, 2021 4:31 PM
To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center; Pet Collars; 5 pm DDL hard

We've had multiple asks for comment on this story. Here's what we would like to run by OPA (Lindsey/Nick) with your approval (see below). Note the "statement" part is the "quotable" part of our responses whereas as the "background" portion is what a reporter can use on background. **Ed/Mike**, I don't know if we can go as far as the highlighted part but I do want to say something about the incident data. -Allison

Statement:

Ex. 5 Deliberative Process (DP)

From: Freedhoff, Michal <Freedhoff.Michal@epa.gov>

Sent: Tuesday, March 2, 2021 12:39 PM

To: Dennis, Allison <Dennis.Allison@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>

Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>

Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Thanks – I'd be interested in what our incident data shows. There have been a number of pet product questions that have come up since I started. Let's discuss whether there is more we could/should be doing at our next OPP general.

Michal Freedhoff, Ph.D.

Acting Assistant Administrator

Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency

Freedhoff.michal@epa.gov

From: Dennis, Allison <Dennis.Allison@epa.gov>

Sent: Tuesday, March 2, 2021 10:53 AM

To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>

Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>

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https://apple.news/A78_uo4GjQWq_FP9GTVxg9w

Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Johnathan Hettinger

Midwest Center for Investigative Reporting

Rhonda Bomwell had never used a flea and tick collar before. Pierre, her 9-year-old Papillon service dog, was mostly an indoor animal.

Still, her veterinarian recommended she purchase one, so Bomwell went to the pet store near her home in Somerset, New Jersey, and selected Bayer's Seresto collar.

A day later, on June 2, 2020, Pierre had a seizure, collapsing while Bomwell was making dinner. Lying on his back, the dog stopped breathing and his eyes rolled back.

Bomwell tried giving him CPR. Then she called the police. An officer helped her lift the dog into her car, and she rushed him to the hospital. Pierre died before he could receive medical treatment. Bomwell didn't think to take off Pierre's collar.

"I just didn't put it together," she said.

Bomwell isn't alone. Seresto, one of the most popular flea and tick collars in the country, has been linked to hundreds of pet deaths, tens of thousands of injured animals and hundreds of harmed humans, [U.S. Environmental Protection Agency documents show](#).

Yet the EPA has done nothing to inform the public of the risks.

Seresto, developed by Bayer and now sold by Elanco, works by releasing small amounts of pesticide onto the animal for months at a time. The pesticide is supposed to kill fleas, ticks and other pests but be safe for cats and dogs.



But thousands of pets are being harmed, according to federal documents obtained through a public records request from the Center for Biological Diversity, a nonprofit organization that watchdogs the EPA as part of its work to protect endangered species. The center provided the documents to the Midwest Center for Investigative Reporting.

Since Seresto flea and tick collars were introduced in 2012, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, including nearly 1,000 involving human harm.

The EPA is in charge of regulating products that contain pesticides. The agency has known about these incidents for years but has not informed the public of the potential risks associated with this product, said Karen McCormack, a retired EPA employee who worked as both a scientist and communications officer.

McCormack said the collars have the most incidents of any pesticide pet product she's ever seen.

"The EPA appears to be turning a blind eye to this problem, and after seven years of an increasing number of incidents, they are telling the public that they are continuing to monitor the situation," she said. "But I think this is a significant problem that needs to be addressed sooner rather than later."



The EPA declined to say how Seresto compares to other pet products. But in response to a question about whether the product is safe, an agency spokesperson said in an emailed statement that the two pesticides in Seresto have “been found eligible for continued registration” based on best available science, including incident data.

“No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk,” the spokesperson said. “The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.”

Amazon, where Seresto is the top-selling collar, also has received numerous complaints about the product from customers who detailed significant issues. Dozens of people over the years have claimed the collar caused skin rashes in their pet. Others said it led to neurological issues in their pets.

Despite the many warnings, Amazon has not removed the product from its online marketplace. Amazon did not respond to multiple requests for comment for this story.

This isn’t the first time that the EPA has failed to properly regulate flea and tick collars containing pesticides, said Miriam Rotkin-Ellman, a senior scientist at the Natural Resources Defense Council.

The NRDC filed a petition against the agency more than a decade ago over its approval of a different pesticide than the one used in Seresto that is linked to cancer and brain development issues in children.

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NRDC has challenged that decision; that lawsuit is currently pending.

Even so, the number of incidents linked to that pesticide pales in comparison to those linked to Seresto. From 1992 to 2008, the EPA received about 4,600 incident reports regarding pet collars containing tetrachlorvinphos, including 363 deaths, according to EPA documents.

Broken down per year, that's 30 times fewer incidents and 10 times fewer deaths than Seresto.

And those are most likely an undercount, said Nathan Donley, a senior scientist at the Center for Biological Diversity and an expert on U.S. pesticide regulation. Donley said the number of reported incidents for Seresto is "just the tip of the iceberg."

In order to report an incident, a person has to make the connection between the collar and the issue with the dog, understand who to contact and how to report it, he said.

"Most of the time, people are not going to make the connection or they're not going to take an hour or so out of the day and figure out how to call and spend time on hold," Donley said.

He said the incident data creates lots of questions about EPA processes.

"My God, if this doesn't trigger a concern, that's a fundamental problem with the process," Donley said. "The fact that EPA has not done anything to alert the public that there might be an issue here, it strikes me as bordering on criminal. The EPA has this system in place to compile information and it's just collecting dust in some database."

A big business

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Collars have caused seizures, rashes in humans

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“It’s really not just happening to animals. It’s happening to people who pet them as well,” Donley said. “I have two young kids who are all over our dog all the time. I can imagine how highly exposed people would be to residues.”

‘It’s just been a nightmare’

To Bomwell, the worst part was the lack of warning. Pierre had never been sick or had a seizure. He was just 9, so she thought he had half a decade left. Her last dog had died at 18. Plus, she felt like she was responsible. She was the one who put the collar on.

“It was so bizarre,” Bomwell said. “It’s just been a nightmare.”

Even if the EPA had not received tens of thousands of complaints, a cursory search of the web would find dozens of posts from pet owners warning others to be careful with the collars, including a letter to an animal doctor column in the St. Louis Post-Dispatch in 2013, a radio news story in New York in 2016 and extensive comments on pet forums.

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Packard created a Facebook page, asking people who had similar issues to share their stories.

Today, the page fills up with pictures and stories like Packard's.

A dog starts wearing a collar. Within weeks, a dog will have a seizure, sometimes it will later die. Other stories aren't quite as extreme. Loss of hair around the neck. Lethargy.

Packard encourages everyone to report their story to the EPA.

“I don't want others to go through what we went through,” he said. “Every time I read the stories, it brings me back to my dogs. But if I can save a few pets, I can deal with it.”

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Message

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 6/24/2019 1:47:10 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]
CC: Davis, Donna [Davis.Donna@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
Subject: FW: Request for Information RE: Seresto Flea and Tick Collar Incident

FYI Seresto

From: Aubee, Catherine
Sent: Monday, June 24, 2019 9:45 AM
To: Wilbur, Donald <Wilbur.Donald@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: Niman, Aaron <niman.aaron@epa.gov>; Borges-Silva, Quentin <Borges-Silva.Quentin@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; Olinger, Christine <Olinger.Christine@epa.gov>; Fehir, Richard <Fehir.Richard@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Rivera-Lupianez, Ana <Rivera-Lupianez.Ana@epa.gov>
Subject: RE: Request for Information RE: Seresto Flea and Tick Collar Incident

Thanks so much! I spoke with Quentin on Friday and also recommended that future inquiries be directed to the NPIC DVM.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Looping in Ana for

awareness re: NPIC.

Best,
Catherine
Chief, OPP RD IVB1

From: Wilbur, Donald
Sent: Monday, June 24, 2019 9:40 AM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: Niman, Aaron <niman.aaron@epa.gov>; Borges-Silva, Quentin <Borges-Silva.Quentin@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; Olinger, Christine <Olinger.Christine@epa.gov>; Fehir, Richard <Fehir.Richard@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>
Subject: RE: Request for Information RE: Seresto Flea and Tick Collar Incident

Folks-

I have drafted a response from HED with the help of the chemical teams. If further questions are brought up I feel that they should be addressed by the OPP pet incident team (which includes DVMs) and/or by contacting the NPIC DVM-Ph.D. for further information. HED does not have the expertise to address these types of questions and is merely stating what has already been published in our risk assessments.

Thanks,
Don

Response:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Donald Wilbur
Acting Deputy Director
U.S. Environmental Protection Agency
Office of Pesticide Programs
Health Effects Division (7509P)
1200 Pennsylvania Ave NW
Washington, DC 20460
Telephone: (703)-347-8894
Email: Wilbur.Donald@epa.gov

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From: Aubee, Catherine
Sent: Friday, June 21, 2019 12:30 PM
To: Miller, David <Miller.DavidJ@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>
Cc: Niman, Aaron <niman.aaron@epa.gov>
Subject: Fwd: Request for Information RE: Seresto Flea and Tick Collar Incident

Ex. 5 Deliberative Process (DP)

Please redirect to the appropriate HED folks if needed.

Begin forwarded message:

From: "Mysz, Amy" <mysz.amy@epa.gov>
Date: June 21, 2019 at 12:27:21 PM EDT
To: "Borges-Silva, Quentin" <Borges-Silva.Quentin@epa.gov>
Cc: "Aubee, Catherine" <Aubee.Catherine@epa.gov>, "Siedschlag, Gregory" <Siedschlag.Gregory@epa.gov>
Subject: RE: Request for Information RE: Seresto Flea and Tick Collar Incident

Thank you,

Ex. 5 Deliberative Process (DP)

From: Borges-Silva, Quentin

Sent: Friday, June 21, 2019 11:03 AM

To: Mysz, Amy <mysz.amy@epa.gov>

Cc: Aubee, Catherine <Aubee.Catherine@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>

Subject: FW: Request for Information RE: Seresto Flea and Tick Collar Incident

Amy,

Here is the response from OPP's Health Effects Division:

Original Information Request:

Can you provide information for this woman (Sarah Crockett) from a veterinary clinic in OH? She contacted Region 5 yesterday about a dog incident involving a flea and tick collar. The dog apparently recovered immediately after the collar was removed, but then died the next day and had no other medical history. She reported it through the NPIC portal (partially pasted below), but *she wants to know if there are any tests that can be done with the corpse – tissues, etc. to help determine whether the collar contributed.*

-

Ex. 5 Deliberative Process (DP)

Let us know if you need more.

Thanks,

Quentin Borges-Silva

EPA's Office of Pesticide Programs

"Protecting Human Health & the Environment"

From: Aubee, Catherine

Sent: Friday, June 21, 2019 11:40 AM

To: Borges-Silva, Quentin <Borges-Silva.Quentin@epa.gov>; Siedschlag, Gregory

<Siedschlag.Gregory@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>

Cc: Eagle, Venus <Eagle.Venus@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>

Subject: RE: Request for Information RE: Seresto Flea and Tick Collar Incident

Thank you, Quentin. This is very helpful. Who will respond to the requester (either directly or via Amy Mysz)?

Please cc: me if you send the response, or let me know if you prefer that I send it.

Best,
Catherine
Chief, OPP RD IVB1

From: Borges-Silva, Quentin

Sent: Friday, June 21, 2019 11:34 AM

To: Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>

Cc: Eagle, Venus <Eagle.Venus@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>

Subject: RE: Request for Information RE: Seresto Flea and Tick Collar Incident

Importance: High

This just in from HED:

Original Information Request:

Can you provide information for this woman (Sarah Crockett) from a veterinary clinic in OH? She contacted Region 5 yesterday about a dog incident involving a flea and tick collar. The dog apparently recovered immediately after the collar was removed, but then died the next day and had no other medical history. She reported it through the NPIC portal (partially pasted below), but *she wants to know if there are any tests that can be done with the corpse – tissues, etc. to help determine whether the collar contributed.*

-

Ex. 5 Deliberative Process (DP)

Quentin Borges-Silva
EPA's Office of Pesticide Programs
"Protecting Human Health & the Environment"

From: Siedschlag, Gregory
Sent: Thursday, June 20, 2019 8:27 AM
To: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Eagle, Venus <Eagle.Venus@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>; Borges-Silva, Quentin <Borges-Silva.Quentin@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: Request for Information RE: Seresto Flea and Tick Collar Incident

Ok, thanks. Very helpful. Quentin will take the lead on this for us – he'll be in touch with any questions.

Best,

Greg Siedschlag
Chief, Communication Services Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency
Phone: (703) 603-9044
Cell: (571) 255-0284
<https://www.epa.gov/pesticides>

From: Rossmeisl, Colleen
Sent: Thursday, June 20, 2019 7:06 AM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>
Cc: Eagle, Venus <Eagle.Venus@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>; Borges-Silva, Quentin <Borges-Silva.Quentin@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: Request for Information RE: Seresto Flea and Tick Collar Incident

Hi Greg –

Yes, that would be my suggestion to loop them into the conversation. I am happy to chat with them to put things in context, I am just not sure who the folks are on the team. And if you can give us a sense of how much detail you want to respond with, I can help if more information is needed.

However, just a note on availability, I am in meetings all day starting at 9, so may not be immediately responsive.

Thanks!
Colleen

From: Aubee, Catherine
Sent: Thursday, June 20, 2019 6:55 AM
To: Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>
Cc: Eagle, Venus <Eagle.Venus@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>; Borges-Silva, Quentin <Borges-Silva.Quentin@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: Re: Request for Information RE: Seresto Flea and Tick Collar Incident

Further, suggestion from Colleen:

Ex. 5 Deliberative Process (DP)

Also looping in PRD.

On Jun 20, 2019, at 6:50 AM, Aubee, Catherine <Aubee.Catherine@epa.gov> wrote:

Thanks, Greg. It's an unusual question. Colleen and Julie (CC'd) may be able to help with technical input. Let me know if there are any regulatory questions.

I took Amy Mysz off the cc list here but we will want to include her when the response is provided.

Best,
Catherine

On Jun 19, 2019, at 11:38 PM, Siedschlag, Gregory <Siedschlag.Gregory@epa.gov> wrote:

Hi Catherine,

We can take the lead, but do you have any thoughts on people who could help us answer this question? I'm still fairly new here and haven't seen a question like this before.

Thanks,

Greg Siedschlag
Chief, Communication Services Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency
Phone: (703) 603-9044
Cell: (571) 255-0284
<https://www.epa.gov/pesticides>

From: Aubee, Catherine
Sent: Wednesday, June 19, 2019 10:29 AM
To: Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>
Cc: Mysz, Amy <mysz.amy@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>
Subject: RE: Request for Information RE: Seresto Flea and Tick Collar Incident

Hi Greg,

Would FEAD like to take the lead on this response? Let us know how we can help.

It is time sensitive given that they are requesting info about biological samples.

Bob, cc'ing you for awareness.

Best,
Catherine
Chief, OPP RD IVB1

From: Mysz, Amy
Sent: Tuesday, June 18, 2019 7:13 PM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Subject: Request for Information RE: Seresto Flea and Tick Collar Incident

Hi,

Can you provide information for this woman (Sarah Crockett) from a veterinary clinic in OH? She contacted Region 5 yesterday about a dog incident involving a flea and tick collar. The dog apparently recovered immediately after the collar was removed, but then died the next day and had no other medical history. She reported it through the NPIC portal (partially pasted below), but she wants to know if there are any tests that can be done with the corpse – tissues, etc. to help determine whether the collar contributed.

The product information she provided is: Seresto Flea and Tick Collar for dogs 18 lbs and over, EPA Registration No. 11556-155, EPA Est No 11556-DEU-1. Active ingredients: Flumethrin 4.5% and Imidacloprid 10%

She would appreciate any direction or suggestions you can provide, if any.

Thanks,
Amy

From: Sarah Crockett <officercrockett@yahoo.com>
Sent: Monday, June 17, 2019 7:13 PM
To: Mysz, Amy <mysz.amy@epa.gov>
Subject: Seresto Flea and Tick Collar

Hello we spoke earlier about a Mastiff who died the day after having a seresto collar put on him. I have submitted a report to the site you recommended. Bayer's veterinarian is insisting the collar could have no way shape or form had any negative impact on the dog despite the necropsy results from The Ohio department of agriculture showing no underlying disease or apparent cause of death and suggests based on the severe congestion on the liver and lung "shock, possibly anaphylactic shock, Is a potential differential". Do you have any suggestions on what else we could possibly test for to prove or disapprove the collar had anything to do with it? Below is pictures of the report I submitted.

<image001.png>

Thank you!

Sarah

Sent from my iPhone

Message

From: Messina, Edward [Messina.Edward@epa.gov]
Sent: 3/2/2021 8:12:36 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]
Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar

Ahh. But we still do this.. OK. Let's see what feedback you get.

Ed Messina, Esq.
Acting Office Director
Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
p: (703) 347-0209

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Tuesday, March 2, 2021 3:11 PM
To: Messina, Edward <Messina.Edward@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar

Ex. 5 Deliberative Process (DP)

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
571-309-5497 (cell)

From: Messina, Edward <Messina.Edward@epa.gov>
Sent: Tuesday, March 02, 2021 3:04 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar

Ex. 5 Deliberative Process (DP)

Ed

Ed Messina, Esq.
Acting Office Director
Office of Pesticide Programs

Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
p: (703) 347-0209

From: Goodis, Michael <Goodis.Michael@epa.gov>

Sent: Tuesday, March 2, 2021 2:19 PM

To: Dennis, Allison <Dennis.Allison@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>

Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar

Ex. 5 Deliberative Process (DP)

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
571-309-5497 (cell)

From: Dennis, Allison <Dennis.Allison@epa.gov>

Sent: Tuesday, March 02, 2021 10:53 AM

To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>

Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>

Subject: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Head's up on this story. We're working up a statement regarding our incident data to use if needed. -Allison

https://apple.news/A78_uo4GIQWq_FP9GTVxg9w

Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Johnathan Hettinger
Midwest Center for Investigative Reporting

Rhonda Bomwell had never used a flea and tick collar before. Pierre, her 9-year-old Papillon service dog, was mostly an indoor animal.

Still, her veterinarian recommended she purchase one, so Bomwell went to the pet store near her home in Somerset, New Jersey, and selected Bayer's Seresto collar.

A day later, on June 2, 2020, Pierre had a seizure, collapsing while Bomwell was making dinner. Lying on his back, the dog stopped breathing and his eyes rolled back.

Bomwell tried giving him CPR. Then she called the police. An officer helped her lift the dog into her car, and she rushed him to the hospital. Pierre died before he could receive medical treatment. Bomwell didn't think to take off Pierre's collar.

"I just didn't put it together," she said.

Bomwell isn't alone. Seresto, one of the most popular flea and tick collars in the country, has been linked to hundreds of pet deaths, tens of thousands of injured animals and hundreds of harmed humans, U.S. Environmental Protection Agency documents show.

Yet the EPA has done nothing to inform the public of the risks.

Seresto, developed by Bayer and now sold by Elanco, works by releasing small amounts of pesticide onto the animal for months at a time. The pesticide is supposed to kill fleas, ticks and other pests but be safe for cats and dogs.



But thousands of pets are being harmed, according to federal documents obtained through a public records request from the Center for Biological Diversity, a nonprofit organization that watchdogs the EPA as part of its work to protect endangered species. The center provided the documents to the Midwest Center for Investigative Reporting.

Since Seresto flea and tick collars were introduced in 2012, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, including nearly 1,000 involving human harm.

The EPA is in charge of regulating products that contain pesticides. The agency has known about these incidents for years but has not informed the public of the potential risks associated with this product, said Karen McCormack, a retired EPA employee who worked as both a scientist and communications officer.

McCormack said the collars have the most incidents of any pesticide pet product she's ever seen.

"The EPA appears to be turning a blind eye to this problem, and after seven years of an increasing number of incidents, they are telling the public that they are continuing to monitor the situation," she said. "But I think this is a significant problem that needs to be addressed sooner rather than later."



The EPA declined to say how Seresto compares to other pet products. But in response to a question about whether the product is safe, an agency spokesperson said in an emailed statement that the two

pesticides in Seresto have “been found eligible for continued registration” based on best available science, including incident data.

“No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk,” the spokesperson said. “The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.”

Amazon, where Seresto is the top-selling collar, also has received numerous complaints about the product from customers who detailed significant issues. Dozens of people over the years have claimed the collar caused skin rashes in their pet. Others said it led to neurological issues in their pets.

Despite the many warnings, Amazon has not removed the product from its online marketplace. Amazon did not respond to multiple requests for comment for this story.

This isn’t the first time that the EPA has failed to properly regulate flea and tick collars containing pesticides, said Miriam Rotkin-Ellman, a senior scientist at the Natural Resources Defense Council.

The NRDC filed a petition against the agency more than a decade ago over its approval of a different pesticide than the one used in Seresto that is linked to cancer and brain development issues in children.

In April 2020, a federal appeals court called the EPA’s refusal to respond to NRDC’s requests “nothing short of egregious” and told agency officials to make a decision on whether to ban the pesticide within 90 days. The EPA decided not to ban the pesticide, called tetrachlorvinphos. That pet collar continues to be sold under the brand name Hartz Ultraguard, Hartz InControl and Longlife.

NRDC has challenged that decision; that lawsuit is currently pending.

Even so, the number of incidents linked to that pesticide pales in comparison to those linked to Seresto. From 1992 to 2008, the EPA received about 4,600 incident reports regarding pet collars containing tetrachlorvinphos, including 363 deaths, according to EPA documents.

Broken down per year, that’s 30 times fewer incidents and 10 times fewer deaths than Seresto.

And those are most likely an undercount, said Nathan Donley, a senior scientist at the Center for Biological Diversity and an expert on U.S. pesticide regulation. Donley said the number of reported incidents for Seresto is “just the tip of the iceberg.”

In order to report an incident, a person has to make the connection between the collar and the issue with the dog, understand who to contact and how to report it, he said.

“Most of the time, people are not going to make the connection or they’re not going to take an hour or so out of the day and figure out how to call and spend time on hold,” Donley said.

He said the incident data creates lots of questions about EPA processes.

“My God, if this doesn't trigger a concern, that's a fundamental problem with the process,” Donley said. “The fact that EPA has not done anything to alert the public that there might be an issue here, it strikes me as bordering on criminal. The EPA has this system in place to compile information and it’s just collecting dust in some database.”

A big business

Pet collars are big business. In its 2019 annual report, German agribusiness and pharmaceutical company Bayer reported revenue of more than \$300 million on Seresto alone.

The company sold its animal health division to Elanco Animal Health, a former subsidiary of Eli Lilly and Co., for \$7.6 billion in 2019. The deal was finalized in 2020. As part of the deal, Bayer received \$2.3 billion in Elanco stock, which the company said it would sell over time.

Bayer did not respond to multiple requests for comment.

Since being spun off as its own company in 2019, Elanco has lobbied the EPA quarterly on issues relating to animal health, according to the the nonprofit Center for Responsive Politics, which maintains a website tracking political contributions. Over two years, the company has spent \$1.6 million on lobbying, records show.

Keri McGrath, a spokeswoman for Elanco, said in an email the company “takes the safety of our products very seriously and thoroughly investigates potential concerns related to their use.” McGrath pointed out that regulatory authorities have approved the product in more than 80 countries, and the EPA is in the final stages of re-approving both pesticides. There is no timeline on the final decision.

McGrath said that global data shows that 1 in 568 users of Seresto have an incident and “the majority of these incident reports relate to non-serious effects such as application site disorders, e.g. a reddening of the skin or hair loss below the collar.”

“Keep in mind that the existence of an adverse event report does not necessarily mean the product caused the problem,” she said. “Causality between the observed signs and the use of the product is evaluated on a case-by-case basis. That said, every adverse event collected, regardless of causality, is reported to the authorities.”



The EPA did not respond to a request about how Seresto compared to other flea and tick collars in terms of incidents. The Midwest Center has filed a Freedom of Information request for the incident database, but that request has not yet been filled.

The extent of the damage is uncommon, said McCormack, the former EPA staffer.

“I’ve never seen any product that had 75,000 incidents,” McCormack said.

Seresto’s pesticides more toxic together

The EPA approved Seresto collars on March 16, 2012. The collars are designed to work for eight months.

Under the Federal Insecticide, Fungicide and Rodenticide Act, the EPA must determine a pesticide product will not cause “unreasonable effects on the environment.”

This determination requires weighing harms versus benefits, including assessments of risks to human health and the environment.

Seresto contains two pesticides: imidacloprid and flumethrin.

Imidacloprid belongs to the neonicotinoid class of insecticides, which are the most commonly used insecticides on crops in the U.S. Despite neonicotinoids being connected to massive die-offs of non-target insects such as bees and butterflies, the EPA proposed re-approving imidacloprid and other class members last year. The pesticide is banned in the European Union for outdoor use but allowed in pet collars. There is also growing evidence that mammals can be harmed by these pesticides as well.

Flumethrin, EPA documents show, is only an active ingredient in one product: Seresto.

Like with most pesticides, the data supporting the registration of Seresto was conducted by the company that produced it, Bayer. The majority of the studies were looking at each pesticide individually.

However, a 2012 Bayer study found they have a “synergistic effect,” meaning they are more toxic together on fleas. The study found that the “unique pharmacological synergism” works as quickly as six hours to prevent ticks from attaching and feeding, preventing disease transmission.

Additionally, eight companion animal safety studies were conducted by Bayer looking at the effect of Seresto collars on domestic cats and dogs. The EPA used these studies to approve Seresto.

The California Department of Pesticide Regulation took issue with the validity of two of the studies but approved the collars anyway.

Another issue could be a reaction of inactive ingredients, which are unknown and have caused problems in spot-on treatments, said Donley of the Center for Biological Diversity.

Donley, who has a doctorate in cell and developmental biology and is a former cancer researcher, said this “synergistic effect” likely extends to pets. He said he wasn’t sure what makes the two pesticides so likely to cause harm, but it is clear something is wrong with the product.

“You don’t even see these kinds of numbers with many agricultural chemicals,” Donley said.

“For whatever reason, this combination is just really nasty.”

History of unsafe pet treatments

There are currently 18 flea and tick collars on the market: three that are approved for both dogs and cats (including Seresto), 10 approved for dogs and five for cats, according to the National Pesticide Information Center.

In addition to allowing tetrachlorvinphos in pet collars despite evidence of its unsafety, the EPA also had approved the use of another pesticide linked to cancer and brain development problems – propoxur, which was sold under many brand names, including Bio Spot, Scratex Color, Zodiac, Sergeant's Dual Action and Sentry Dual Action.

Rotkin-Ellman's research showed residues were high enough to pose a risk to children and adults who play with pets that were wearing the collars.

In April 2016, pesticide companies voluntarily agreed to stop using propoxur to help protect children's health. The brand names that used propoxur have switched to other active ingredients.

In addition, in 2010, the EPA increased label requirements and limited some inert ingredients in spot-on treatments, which are applied to a specific area of a pet. This happened after incident data showed the treatments were causing hundreds of pet deaths, as well as issues such as irritation, rashes and hair loss, gastrointestinal problems and seizures.

Collars have caused seizures, rashes in humans

It's not just pets that are being harmed, EPA documents show.

Between 2013 and 2018, 907 incidents were reported with humans, according to a September 2019 EPA assessment of human health risk.

The assessment determined that there were 19 severe incidents. Of those, eight people had dermal symptoms, such as a rash or hives, and seven had neurological symptoms, which included numbness and headaches.

Incidents listed by the EPA included:

- A 12-year-old boy who slept in a bed with a dog wearing a collar started having seizures and vomiting. He had to be hospitalized.
- A 67-year-old woman who slept in a bed with a dog wearing a collar reported having heart arrhythmia and fatigue.
- A 43-year-old man put collars on eight dogs and slept in the same bed as four of the dogs. A week later, he developed ear drainage and nasal and throat irritation and was told by a doctor that he had a hole in his ear drum. He removed the dog collars and the symptoms went away. He later reapplied the collars and the symptoms returned.

An October 2016 EPA bulletin responded to citizen concerns about children being exposed to Seresto, saying it had found exposure to the collars to be negligible.

“As stated in the precautions on the label, do not allow children to play with the collars. In addition, try to keep the pet away from young children for a day after putting on the collar to minimize exposure,” the bulletin said.

“It’s really not just happening to animals. It’s happening to people who pet them as well,” Donley said. “I have two young kids who are all over our dog all the time. I can imagine how highly exposed people would be to residues.”

‘It’s just been a nightmare’

To Bomwell, the worst part was the lack of warning. Pierre had never been sick or had a seizure. He was just 9, so she thought he had half a decade left. Her last dog had died at 18. Plus, she felt like she was responsible. She was the one who put the collar on.

“It was so bizarre,” Bomwell said. “It’s just been a nightmare.”

Even if the EPA had not received tens of thousands of complaints, a cursory search of the web would find dozens of posts from pet owners warning others to be careful with the collars, including a letter to an animal doctor column in the St. Louis Post-Dispatch in 2013, a radio news story in New York in 2016 and extensive comments on pet forums.

Without the federal government stepping in, individuals are left in the dark. That’s something Ron Packard, of Brockton, Massachusetts, is hoping to address.

In the days after the death of his two dogs in June 2019, Packard did what any person looking for answers does: He went to the internet.

Two of Packard’s four dogs had recently had seizures on the same day, before becoming lethargic and vomiting and finally, refusing to eat. He brought them to the veterinarian, who couldn’t find a problem.

Within weeks, the two previously healthy cavachons, 10-year-old Danny and 5-year-old Dominic, were both dead.



The only thing Packard could figure out was both dogs had started wearing Seresto flea and tick collars a month before.

“Thirty-three and 54 days later, they're both dead,” Packard said.

Packard created a Facebook page, asking people who had similar issues to share their stories.

Today, the page fills up with pictures and stories like Packard's.

A dog starts wearing a collar. Within weeks, a dog will have a seizure, sometimes it will later die. Other stories aren't quite as extreme. Loss of hair around the neck. Lethargy.

Packard encourages everyone to report their story to the EPA.

“I don't want others to go through what we went through,” he said. “Every time I read the stories, it brings me back to my dogs. But if I can save a few pets, I can deal with it.”

This story is a collaboration between USA TODAY and the Midwest Center for Investigative Reporting. The center is an independent, nonprofit newsroom covering agribusiness, Big Ag and related issues. USA TODAY is funding a fellowship at the center for expanded coverage of agribusiness and its impact on communities.

Message

From: Ozmen, Shamus [Ozmen.Shamus@epa.gov]
Sent: 3/2/2021 6:14:17 PM
To: Messina, Edward [Messina.Edward@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]
CC: Siedschlag, Gregory [Siedschlag.Gregory@epa.gov]; Overbey, Dian [Overbey.Dian@epa.gov]
Subject: FW: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.
Attachments: FW: Seresto - Midwest Center for Investigative Reporting; EPA-HQ-OPP-2016-0031-0031.pdf; Aggregate Incident Summary Report for EPA Reg No 11556-155 1-1-2012 to 6-16-2020.pdf; RE: OPS MEDIA INQUIRY : SERESTO - query from a NY Post reporter

Hi Ed and Mike –

For convenience, I'm attaching the data that was referenced, our prior response to Midwest and the new inquiry from NY Post.

Dian is working on the new press inquiry now.

Thanks,
Shamus

From: Freedhoff, Michal <Freedhoff.Michal@epa.gov>
Sent: Tuesday, March 2, 2021 12:39 PM
To: Dennis, Allison <Dennis.Allison@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>
Subject: RE: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Thanks – I'd be interested in what our incident data shows. There have been a number of pet product questions that have come up since I started. Let's discuss whether there is more we could/should be doing at our next OPP general.

Michal Freedhoff, Ph.D.
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Freedhoff.michal@epa.gov

From: Dennis, Allison <Dennis.Allison@epa.gov>
Sent: Tuesday, March 2, 2021 10:53 AM
To: Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>
Subject: 3/2 USA Today/Midwest Center for Investigative Reporting: Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Head's up on this story. We're working up a statement regarding our incident data to use if needed. -Allison

https://apple.news/A78_uo4GjQWq_FP9GTVxg9w

Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Johnathan Hettinger

Midwest Center for Investigative Reporting

Rhonda Bomwell had never used a flea and tick collar before. Pierre, her 9-year-old Papillon service dog, was mostly an indoor animal.

Still, her veterinarian recommended she purchase one, so Bomwell went to the pet store near her home in Somerset, New Jersey, and selected Bayer's Seresto collar.

A day later, on June 2, 2020, Pierre had a seizure, collapsing while Bomwell was making dinner. Lying on his back, the dog stopped breathing and his eyes rolled back.

Bomwell tried giving him CPR. Then she called the police. An officer helped her lift the dog into her car, and she rushed him to the hospital. Pierre died before he could receive medical treatment. Bomwell didn't think to take off Pierre's collar.

"I just didn't put it together," she said.

Bomwell isn't alone. Seresto, one of the most popular flea and tick collars in the country, has been linked to hundreds of pet deaths, tens of thousands of injured animals and hundreds of harmed humans, U.S. Environmental Protection Agency documents show.

Yet the EPA has done nothing to inform the public of the risks.

Seresto, developed by Bayer and now sold by Elanco, works by releasing small amounts of pesticide onto the animal for months at a time. The pesticide is supposed to kill fleas, ticks and other pests but be safe for cats and dogs.



But thousands of pets are being harmed, according to federal documents obtained through a public records request from the Center for Biological Diversity, a nonprofit organization that watchdogs the EPA as part of its work to protect endangered species. The center provided the documents to the Midwest Center for Investigative Reporting.

Since Seresto flea and tick collars were introduced in 2012, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, including nearly 1,000 involving human harm.

The EPA is in charge of regulating products that contain pesticides. The agency has known about these incidents for years but has not informed the public of the potential risks associated with this product, said Karen McCormack, a retired EPA employee who worked as both a scientist and communications officer.

McCormack said the collars have the most incidents of any pesticide pet product she's ever seen.

"The EPA appears to be turning a blind eye to this problem, and after seven years of an increasing number of incidents, they are telling the public that they are continuing to monitor the situation," she said. "But I think this is a significant problem that needs to be addressed sooner rather than later."



The EPA declined to say how Seresto compares to other pet products. But in response to a question about whether the product is safe, an agency spokesperson said in an emailed statement that the two pesticides in Seresto have “been found eligible for continued registration” based on best available science, including incident data.

“No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk,” the spokesperson said. “The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.”

Amazon, where Seresto is the top-selling collar, also has received numerous complaints about the product from customers who detailed significant issues. Dozens of people over the years have claimed the collar caused skin rashes in their pet. Others said it led to neurological issues in their pets.

Despite the many warnings, Amazon has not removed the product from its online marketplace. Amazon did not respond to multiple requests for comment for this story.

This isn’t the first time that the EPA has failed to properly regulate flea and tick collars containing pesticides, said Miriam Rotkin-Ellman, a senior scientist at the Natural Resources Defense Council.

The NRDC filed a petition against the agency more than a decade ago over its approval of a different pesticide than the one used in Seresto that is linked to cancer and brain development issues in children.

In April 2020, a federal appeals court called the EPA's refusal to respond to NRDC's requests "nothing short of egregious" and told agency officials to make a decision on whether to ban the pesticide within 90 days. The EPA decided not to ban the pesticide, called tetrachlorvinphos. That pet collar continues to be sold under the brand name Hartz Ultraguard, Hartz InControl and Longlife.

NRDC has challenged that decision; that lawsuit is currently pending.

Even so, the number of incidents linked to that pesticide pales in comparison to those linked to Seresto. From 1992 to 2008, the EPA received about 4,600 incident reports regarding pet collars containing tetrachlorvinphos, including 363 deaths, according to EPA documents.

Broken down per year, that's 30 times fewer incidents and 10 times fewer deaths than Seresto.

And those are most likely an undercount, said Nathan Donley, a senior scientist at the Center for Biological Diversity and an expert on U.S. pesticide regulation. Donley said the number of reported incidents for Seresto is "just the tip of the iceberg."

In order to report an incident, a person has to make the connection between the collar and the issue with the dog, understand who to contact and how to report it, he said.

"Most of the time, people are not going to make the connection or they're not going to take an hour or so out of the day and figure out how to call and spend time on hold," Donley said.

He said the incident data creates lots of questions about EPA processes.

"My God, if this doesn't trigger a concern, that's a fundamental problem with the process," Donley said. "The fact that EPA has not done anything to alert the public that there might be an issue here, it strikes me as bordering on criminal. The EPA has this system in place to compile information and it's just collecting dust in some database."

A big business

Pet collars are big business. In its 2019 annual report, German agribusiness and pharmaceutical company Bayer reported revenue of more than \$300 million on Seresto alone.

The company sold its animal health division to Elanco Animal Health, a former subsidiary of Eli Lilly and Co., for \$7.6 billion in 2019. The deal was finalized in 2020. As part of the deal, Bayer received \$2.3 billion in Elanco stock, which the company said it would sell over time.

Bayer did not respond to multiple requests for comment.

Since being spun off as its own company in 2019, Elanco has lobbied the EPA quarterly on issues relating to animal health, according to the the nonprofit Center for Responsive Politics, which maintains a website tracking political contributions. Over two years, the company has spent \$1.6 million on lobbying, records show.

Keri McGrath, a spokeswoman for Elanco, said in an email the company “takes the safety of our products very seriously and thoroughly investigates potential concerns related to their use.” McGrath pointed out that regulatory authorities have approved the product in more than 80 countries, and the EPA is in the final stages of re-approving both pesticides. There is no timeline on the final decision.

McGrath said that global data shows that 1 in 568 users of Seresto have an incident and “the majority of these incident reports relate to non-serious effects such as application site disorders, e.g. a reddening of the skin or hair loss below the collar.”

“Keep in mind that the existence of an adverse event report does not necessarily mean the product caused the problem,” she said. “Causality between the observed signs and the use of the product is evaluated on a case-by-case basis. That said, every adverse event collected, regardless of causality, is reported to the authorities.”



The EPA did not respond to a request about how Seresto compared to other flea and tick collars in terms of incidents. The Midwest Center has filed a Freedom of Information request for the incident database, but that request has not yet been filled.

The extent of the damage is uncommon, said McCormack, the former EPA staffer.

“I’ve never seen any product that had 75,000 incidents,” McCormack said.

Seresto’s pesticides more toxic together

The EPA approved Seresto collars on March 16, 2012. The collars are designed to work for eight months.

Under the Federal Insecticide, Fungicide and Rodenticide Act, the EPA must determine a pesticide product will not cause “unreasonable effects on the environment.”

This determination requires weighing harms versus benefits, including assessments of risks to human health and the environment.

Seresto contains two pesticides: imidacloprid and flumethrin.

Imidacloprid belongs to the neonicotinoid class of insecticides, which are the most commonly used insecticides on crops in the U.S. Despite neonicotinoids being connected to massive die-offs of non-target insects such as bees and butterflies, the EPA proposed re-approving imidacloprid and

other class members last year. The pesticide is banned in the European Union for outdoor use but allowed in pet collars. There is also growing evidence that mammals can be harmed by these pesticides as well.

Flumethrin, EPA documents show, is only an active ingredient in one product: Seresto.

Like with most pesticides, the data supporting the registration of Seresto was conducted by the company that produced it, Bayer. The majority of the studies were looking at each pesticide individually.

However, a 2012 Bayer study found they have a “synergistic effect,” meaning they are more toxic together on fleas. The study found that the “unique pharmacological synergism” works as quickly as six hours to prevent ticks from attaching and feeding, preventing disease transmission.

Additionally, eight companion animal safety studies were conducted by Bayer looking at the effect of Seresto collars on domestic cats and dogs. The EPA used these studies to approve Seresto. The California Department of Pesticide Regulation took issue with the validity of two of the studies but approved the collars anyway.

Another issue could be a reaction of inactive ingredients, which are unknown and have caused problems in spot-on treatments, said Donley of the Center for Biological Diversity.

Donley, who has a doctorate in cell and developmental biology and is a former cancer researcher, said this “synergistic effect” likely extends to pets. He said he wasn’t sure what makes the two pesticides so likely to cause harm, but it is clear something is wrong with the product.

“You don’t even see these kinds of numbers with many agricultural chemicals,” Donley said.

“For whatever reason, this combination is just really nasty.”

History of unsafe pet treatments

There are currently 18 flea and tick collars on the market: three that are approved for both dogs and cats (including Seresto), 10 approved for dogs and five for cats, according to the National Pesticide Information Center.

In addition to allowing tetrachlorvinphos in pet collars despite evidence of its unsafety, the EPA also had approved the use of another pesticide linked to cancer and brain development problems – propoxur, which was sold under many brand names, including Bio Spot, Scratex Color, Zodiac, Sergeant’s Dual Action and Sentry Dual Action.

Rotkin-Ellman's research showed residues were high enough to pose a risk to children and adults who play with pets that were wearing the collars.

In April 2016, pesticide companies voluntarily agreed to stop using propoxur to help protect children's health. The brand names that used propoxur have switched to other active ingredients.

In addition, in 2010, the EPA increased label requirements and limited some inert ingredients in spot-on treatments, which are applied to a specific area of a pet. This happened after incident data showed the treatments were causing hundreds of pet deaths, as well as issues such as irritation, rashes and hair loss, gastrointestinal problems and seizures.

Collars have caused seizures, rashes in humans

It's not just pets that are being harmed, EPA documents show.

Between 2013 and 2018, 907 incidents were reported with humans, according to a September 2019 EPA assessment of human health risk.

The assessment determined that there were 19 severe incidents. Of those, eight people had dermal symptoms, such as a rash or hives, and seven had neurological symptoms, which included numbness and headaches.

Incidents listed by the EPA included:

- A 12-year-old boy who slept in a bed with a dog wearing a collar started having seizures and vomiting. He had to be hospitalized.
- A 67-year-old woman who slept in a bed with a dog wearing a collar reported having heart arrhythmia and fatigue.
- A 43-year-old man put collars on eight dogs and slept in the same bed as four of the dogs. A week later, he developed ear drainage and nasal and throat irritation and was told by a doctor that he had a hole in his ear drum. He removed the dog collars and the symptoms went away. He later reapplied the collars and the symptoms returned.

An October 2016 EPA bulletin responded to citizen concerns about children being exposed to Seresto, saying it had found exposure to the collars to be negligible.

"As stated in the precautions on the label, do not allow children to play with the collars. In addition, try to keep the pet away from young children for a day after putting on the collar to minimize exposure," the bulletin said.

“It’s really not just happening to animals. It’s happening to people who pet them as well,” Donley said. “I have two young kids who are all over our dog all the time. I can imagine how highly exposed people would be to residues.”

‘It’s just been a nightmare’

To Bomwell, the worst part was the lack of warning. Pierre had never been sick or had a seizure. He was just 9, so she thought he had half a decade left. Her last dog had died at 18. Plus, she felt like she was responsible. She was the one who put the collar on.

“It was so bizarre,” Bomwell said. “It’s just been a nightmare.”

Even if the EPA had not received tens of thousands of complaints, a cursory search of the web would find dozens of posts from pet owners warning others to be careful with the collars, including a letter to an animal doctor column in the St. Louis Post-Dispatch in 2013, a radio news story in New York in 2016 and extensive comments on pet forums.

Without the federal government stepping in, individuals are left in the dark. That’s something Ron Packard, of Brockton, Massachusetts, is hoping to address.

In the days after the death of his two dogs in June 2019, Packard did what any person looking for answers does: He went to the internet.

Two of Packard’s four dogs had recently had seizures on the same day, before becoming lethargic and vomiting and finally, refusing to eat. He brought them to the veterinarian, who couldn’t find a problem.

Within weeks, the two previously healthy cavachons, 10-year-old Danny and 5-year-old Dominic, were both dead.



The only thing Packard could figure out was both dogs had started wearing Seresto flea and tick collars a month before.

“Thirty-three and 54 days later, they're both dead,” Packard said.

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A dog starts wearing a collar. Within weeks, a dog will have a seizure, sometimes it will later die. Other stories aren't quite as extreme. Loss of hair around the neck. Lethargy.

Packard encourages everyone to report their story to the EPA.

“I don't want others to go through what we went through,” he said. “Every time I read the stories, it brings me back to my dogs. But if I can save a few pets, I can deal with it.”

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From: Dennis, Allison [Dennis.Allison@epa.gov]
Sent: 2/12/2021 1:17:10 PM
To: Labbe, Ken [Labbe.Ken@epa.gov]; Press [Press@epa.gov]
CC: Overbey, Dian [Overbey.Dian@epa.gov]; Siedschlag, Gregory [Siedschlag.Gregory@epa.gov]; Ozmen, Shamus [Ozmen.Shamus@epa.gov]
Subject: FW: Seresto - Midwest Center for Investigative Reporting

Michal approved response . -Allison

- 1. According to a records request of EPA documents, there have been at least 75,000 incident reports involving pets, including 1,698 deaths. Is this a high number? Why is it still sold? Is there any sort of threshold for removing the collar from the market?**
- 2. California toxicologists said the Bayer studies the EPA relied on to approve the collars underestimated the harm to adult dogs and cats. However, the EPA approved them. What science is there to support these registrations? How can customers know that these are safe to use?**

Combined Response to the above questions:

The active ingredients in the Seresto collar are flumethrin and imidacloprid. Both have undergone registration review (examination of active ingredients every 15 years to make sure they continue to meet the FIFRA standard for registration), On the basis of current information, both have been found eligible for continued registration. During the registration and registration review processes, the Agency uses the best available science to reach its decision. This includes articles in peer-reviewed journals in addition to the studies submitted by the registrant.

EPA takes every incident reported seriously. If any pesticide is found to present unreasonable adverse effects on the environment as defined in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), or is found not to be safe under the Federal Food, Drug and Cosmetic Act, the Agency would take appropriate regulatory action. Any such action would, again, need to be supported by the best-available, peer-reviewed science. Regulatory action might include anything from changing the label instructions for use to cancelling the registration.

On the Registration process: Under FIFRA, EPA must make a determination that the product will not cause "unreasonable adverse effects on the environment," defined in FIFRA 2(bb) as (in part) "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Thus, the benefits of a product must be weighed against the risks.

To reach a registration decision and inform the label language, the data that EPA requires includes data on pesticide residues, toxicology, companion animal safety, and efficacy. EPA then independently reviews those data to inform the registration decision. EPA uses this information to determine if and how a product may be used. Evaluations for pet products like shampoos, collars and spot-ons rely upon data on companion animal safety, efficacy and safety for humans who may be exposed as a result of product use.

No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk. The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.

3. **It is my understanding that these incidents do not include the main incident reporting system, which likely has additional incidents. Do you have more information about the number of incidents?**

Manufacturers are required under law to report adverse incident information to EPA. Individuals may report incidents potentially associated with use of an EPA-registered product by contacting the product manufacturer, their state lead pesticide agency, the National Pesticide Information Center, or by contacting EPA directly through its Incident Data System.

4. **There have been at least 907 human-related incidents since 2013, according to EPA data. Is this a high number? Is there any sort of threshold for removing the collar from the market?**

As stated in the Flumethrin: Tier I Update Review of Human Incidents and Epidemiology for Proposed Interim Decision, dated Sept. 17, 2019, there was a total of 626 incidents in EPA's Main and Aggregate IDSs. While some major incidents were reported (including dermal and neurological symptoms), the vast majority of the incidents were classified as moderate or lower in severity.

EPA also conducted a larger epidemiological analysis of human incident data associated with pyrethroids ([Pyrethroids: Tier II Epidemiological Report](#), dated April 30, 2019) and found little substantive evidence to suggest a clear, associative or causal relationship between exposure to pyrethroids and adverse effects. EPA will continue to evaluate incident data in future cycles of registration review. EPA may initiate action at any time to address concerns if unreasonable adverse effects are identified. Such actions can range from mandatory label changes to cancellation of the registration.

5. **It is my understanding that Bayer knew about these incidents for years, prior to selling dog collars to Elanco. Did Bayer make Elanco aware of these issues when selling the product to Elanco?**

EPA does not have information on communications between Bayer and Elanco.

6. **From my understanding talking with former EPA staff, Health Canada denied to approve Seresto because of the incident data. Do you have any response to this?**

EPA cannot speak to Health Canada's decisionmaking process related to the Seresto collar. While the Seresto collar is not registered in Canada, it is registered in most countries in the European Union and Australia.

From: Johnathan Hettinger <jhettinger@investigatemitwest.org>

Sent: Tuesday, January 26, 2021 4:05 PM

To: Press <Press@epa.gov>; Daguiard, Robert <Daguiard.Robert@epa.gov>; Labbe, Ken <Labbe.Ken@epa.gov>; Jones, Enesta <Jones.Enesta@epa.gov>

Subject: Seresto - Midwest Center for Investigative Reporting

Hello,

I'm a reporter with the Midwest Center for Investigative Reporting, a nonprofit newsroom based in Champaign, Illinois, that covers agribusiness. I am working on a story about EPA incident data surrounding Seresto collars. It is my understanding that there have been a significant amount of incidents surrounding the pesticides in the collars, and I had some questions.

According to a records request of EPA documents, there have been at least 75,000 incident reports involving pets, including 1,698 deaths. Is this a high number? Why is it still sold? Is there any sort of threshold for removing the collar from the market?

It is my understanding that these incidents do not include the main incident reporting system, which likely has additional incidents. Do you have more information about the number of incidents?

California toxicologists said the Bayer studies the EPA relied on to approve the collars underestimated the harm to adult dogs and cats. However, the EPA approved them. What science is there to support these registrations? How can customers know that these are safe to use?

There have been at least 907 human-related incidents since 2013, according to EPA data. Is this a high number? Is there any sort of threshold for removing the collar from the market?

It is my understanding that Bayer knew about these incidents for years, prior to selling dog collars to Elanco. Did Bayer make Elanco aware of these issues when selling the product to Elanco?

From my understanding talking with former EPA staff, Health Canada denied to approve Seresto because of the incident data. Do you have any response to this?

If possible, I would very much like to speak to someone for this story. Please let me know if you would have some time. My deadline is Friday, end-of-day.

Thanks,
Johnathan Hettinger
Investigative Reporter
Midwest Center for Investigative Reporting
217-493-9791



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: September 17, 2019

SUBJECT: **Flumethrin:** Tier I Update Review of Human Incidents and Epidemiology for
Proposed Interim Decision

PC Code: 036007
Decision No.: 555349
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID No.: NA

DP Barcode: D454235
Registration No.: NA
Regulatory Action: NA
Case No.: NA
CAS No.: 69770-45-2
40 CFR: NA

Ver. Apr. 08

FROM: Shanna Recore, Industrial Hygienist
Toxicology and Epidemiology Branch
Health Effects Division (7509P)

THROUGH: David J. Miller, Acting Branch Chief
Toxicology and Epidemiology Branch
Health Effects Division (7509P)

TO: Julie Van Alstine, Branch Chief
Risk Assessment Branch VI
Health Effects Division (7509P)
and
Rachel Fletcher, Chemical Review Manager
Risk Management & Implementation Branch 5
Pesticide Re-evaluation Division (7508P)

Summary and Conclusions

Flumethrin incidents were previously reviewed in 2016 (S. Recore and E. Evans, D435503, 9/7/2016). At that time, the Agency stated that it would continue to monitor the incident data due to the fact that the only flumethrin end use product (Seresto Collar, Registration No. 11556-155) was a relatively new product that was registered on March 16, 2012..

In the current IDS analysis from January 1, 2016 to August 27, 2019, 252 flumethrin human incidents were reported to Main IDS; there were 374 flumethrin human incidents reported to

Aggregate IDS. A query of SENSOR-Pesticides 1998-2015 identified three cases involving flumethrin. A query of NPIC from 2016 to August 14, 2019, identified three flumethrin cases.

The Agricultural Health Study (AHS) is a federally-funded study that evaluates associations between pesticide exposures and cancer and other health outcomes and represents a collaborative effort between the US National Cancer Institute (NCI), National Institute of Environmental Health Sciences (NIEHS), CDC's National Institute of Occupational Safety and Health (NIOSH), and the US EPA. Flumethrin is not included in the AHS, and therefore this study does not provide information for this report.

The Agency will continue to monitor the incident data and if a concern is triggered, additional analysis will be conducted.

Detailed Review

I. ACTION REQUESTED

Flumethrin is being considered under the FQPA-mandated Registration Review program established to review, on a 15-year cycle, pesticides for which a Re-registration Eligibility Decision has been made. Pesticide Re-Evaluation Division's, RMIB 5 has requested that TEB conduct a Tier I Update review summary of recent incident data from IDS, SENSOR, and NPIC. One component of the Agency's Registration Review Program is consideration of human incident data. In conjunction with a human health risk assessment based on other data sources, such human incident data can assist the Agency in better defining and characterizing the risk of pesticides/pesticide products.

It is important to remember that reports of adverse health effects allegedly due to a specific pesticide exposure (*i.e.*, an "incident") are largely self-reported and therefore, generally speaking, neither exposure to a pesticide or reported symptom (or the connection between the two) is validated or otherwise confirmed. Typically, causation cannot be determined based on incident data, and such data should be interpreted with caution. Nonetheless, incident information can be an important source of feedback to the Agency: incidents of severe outcome, or a suggested pattern or trend among less severe incidents, can signal the Agency to further investigate a particular chemical or product. Epidemiology studies can also be useful and relate the risk of disease, *e.g.*, cancer, and exposure to an agent such as a pesticide product in the general population or specific sub-groups like pesticide applicators.

II. BACKGROUND

Flumethrin is a synthetic pyrethroid insecticide. Flumethrin has one end use product (Seresto Collar, Registration No. 11556-155) which was registered by the Agency on March 16, 2012. This product, which also contains imidacloprid, is an eight-month collar used on dogs and cats for flea and tick control.

For this evaluation, both OPP Incident Data System (IDS), the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event

Notification System for Occupational Risk-Pesticides (SENSOR) and National Pesticide Information Center (NPIC) databases were consulted for pesticide incident data on the active ingredient flumethrin (PC Code:036007). The purpose of the database search is to identify potential patterns in the frequency and severity of the health effects attributed to flumethrin exposure.

III. RESULTS/DISCUSSION

a. IDS (Incident Data System)

OPP's IDS includes reports of alleged human health incidents from various sources, including mandatory Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 6(a)(2) reports from registrants, other federal and state health and environmental agencies, and individual consumers. Since 1992, OPP has compiled these reports in IDS. IDS contains reports from across the U.S. and most incidents have all relevant product information recorded. Reports submitted to the IDS represent anecdotal reports or allegations only, unless otherwise stated in the report.

IDS records incidents in one of two modules: Main IDS and Aggregate IDS:

- Main IDS generally contains incidents resulting in higher severity outcomes and provides more detail with regard to case specifics.¹ This system stores incident data for death, major and moderate incidents, and it includes information about the location, date and nature of the incident. Main IDS incidents involving only one pesticide are considered to provide more certain information about the potential effects of exposure from the pesticide.
- Aggregate IDS contains incidents resulting in less severe human incidents (minor, unknown, or no effects outcomes). These are reported by registrants only as counts in what are aggregate summaries.

For the Main IDS for the three years from January 1, 2016 to August 27, 2019, there were 252 incidents reported that involved the active ingredient flumethrin. Nineteen of these incidents were classified as major severity. Narrative information for these 19 incidents and is found in Appendix A. Two hundred and thirty-three incidents were classified as moderate severity.

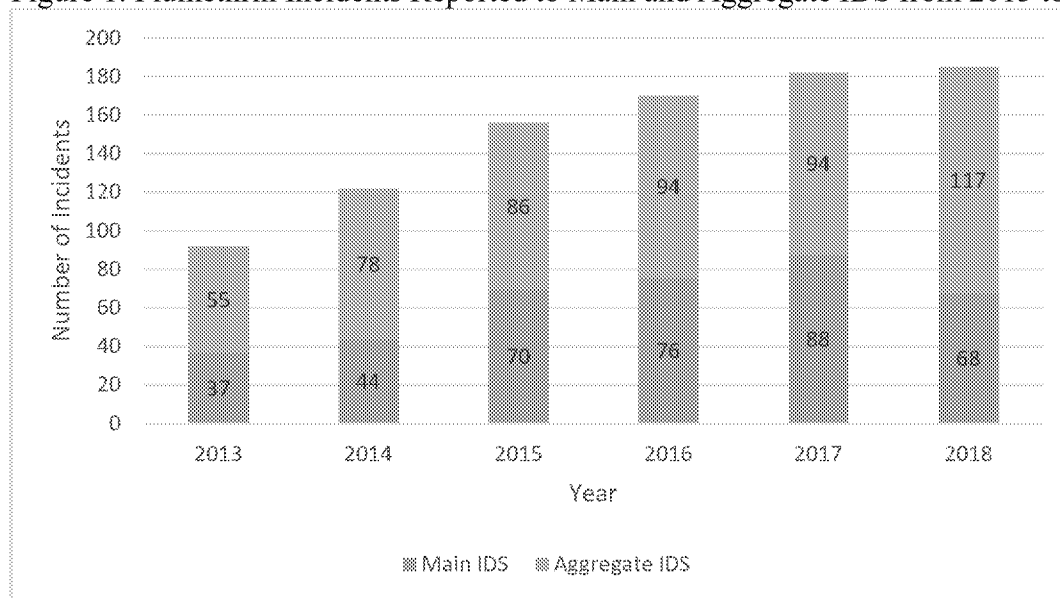
For the Aggregate IDS for the three years from January 1, 2016 to August 27, 2019, there were 374 incidents reported involving flumethrin. These incidents were classified as minor severity.

All the incidents reported to IDS involved Registration No. 11556-155 (Seresto Collar) which contains 4.5% flumethrin and 10% imidacloprid. Seresto Collar is used in dogs and cats to control fleas and ticks.

The total number of flumethrin incidents reported to Main and Aggregate IDS, from 2013 to 2018, appears to be increasing over time (Figure 1).

¹ Occasionally, low severity incidents are self-reported by the consumer directly to Main IDS.

Figure 1. Flumethrin Incidents Reported to Main and Aggregate IDS from 2013 to 2018



Of the 19 major severity incidents that were further reviewed, the symptoms most often reported were dermal (n=8) and neurological (n=7). Note that a patient could exhibit multiple symptoms. Dermal symptoms reported include rash, redness, skin lesions, hives, and pruritus. Neurological symptoms reported include headaches, numbness, tingling and one person reported seizures.

b. SENSOR-Pesticides

The Center for Disease Control's National Institute for Occupational Safety and Health (CDC/NIOSH) manages a pesticide surveillance program and database entitled the Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides.² All cases must report at least two adverse health effects. Evidence for each case is evaluated for its causal relationship between exposure and illness based on the NIOSH case classification index.³ Using standardized protocol and case definitions, SENSOR-Pesticides state coordinators, operating out of the state's department of health, receive state pesticide incident reports from local sources, then follow up with case sources to get incident scenario to obtain medical records and verify exposure scenario information.⁴ This database includes pesticide illness case reports from multiple states from 1998-2015.⁵

A query of SENSOR-Pesticides from 2013-2015 identified three cases involving flumethrin. The three incidents were classified as low severity and are described in Appendix B.

² SENSOR-Pesticides webpage: <http://www.cdc.gov/niosh/topics/pesticides/overview.html>.

³ <https://www.cdc.gov/niosh/topics/pesticides/pdfs/casedef.pdf>

⁴ <https://www.cdc.gov/niosh/topics/pesticides/pdfs/pest-sevindexv6.pdf>

⁵ Currently participating states are: California, Florida, Illinois, Louisiana, Michigan, Nebraska, New Mexico, North Carolina, Oregon, Texas and Washington. The participating states for a given year vary depending on state and federal funding for pesticide surveillance.

c. National Pesticide Information Center (NPIC)

The National Pesticide Information Center or NPIC is a cooperative effort between Oregon State University and EPA which is funded by EPA to serve as a source of objective, science-based pesticide information and respond to inquiries from the public and to incidents. NPIC functions nationally through a toll-free telephone number in addition to the internet (www.npic.orst.edu) and email. Similar to Poison Control Centers, NPIC's primary purpose is not to collect incident data, but rather to provide information to inquirers on a wide range of pesticide topics, and direct callers for pesticide incident investigation and emergency treatment. Nevertheless, NPIC does collect information about incidents (approximately 4000 incidents per year) from inquirers and records that information in a database. NPIC is a source of national incident information but generally receives fewer reports than IDS. Regardless, if a high frequency is observed in IDS, NPIC provides an additional source of information to see whether there is evidence of consistency across national data sets or possibly duplication and additional information about the same incident(s).

From January 1, 2016 to August 14, 2019, three human incidents involving flumethrin were reported to NPIC. One incident was classified as inconsistent with flumethrin exposure and one incident was asymptomatic. These incidents were not further reviewed. The third incident was classified as minor severity. This incident involved a 74-year-old male that was exposed to the collar when a dog that was staying with him got into his bed. The following night he broke out in hives and was itching uncontrollably. He went to the ER and was treated with prednisone. He went home for 24-48 hours, had the same reaction, and went to the ER a second time. After the collar was removed from the dog he had no further symptoms. His wife (age unknown) was also sleeping in the bed and she had no symptoms.

d. Agricultural Health Study (AHS)

The AHS is a federally-funded study that evaluates associations between pesticide exposures and cancer and other health outcomes and represents a collaborative effort between the US National Cancer Institute (NCI), National Institute of Environmental Health Sciences (NIEHS), CDC's National Institute of Occupational Safety and Health (NIOSH), and the US EPA. The AHS participant cohort includes more than 89,000 licensed commercial and private pesticide applicators and their spouses from Iowa and North Carolina. Enrollment occurred from 1993 – 1997, and data collection is ongoing. The AHS maintains a list of publications resulting from AHS studies⁶. If there are AHS findings in the published literature relevant to a pesticide undergoing registration review, the Agency will ensure these findings are considered in the problem formulation/scoping phase of the registration review process and, if appropriate, fully reviewed in the risk assessment phase of the process. Flumethrin is not included in the AHS, and therefore this study does not provide information for this report.

⁶ Agricultural Health Study: Publications <https://aghealth.nih.gov/news/publications.html>

IV. CONCLUSION

Flumethrin is the active ingredient in only one end use product (Seresto Collar, Registration No. 11556-155) that was registered on March 16, 2012. This product is a pet collar used on dogs and cats to control fleas and ticks. It contains the active ingredients flumethrin and imidacloprid.

IDS, SENSOR-Pesticides, and NPIC databases were queried for flumethrin incidents. There were 252 flumethrin incidents reported to Main IDS and 374 flumethrin incidents reported to Aggregate IDS from January 1, 2016 to August 27, 2019. Nineteen of these incidents were classified a major severity, 233 incidents were classified as moderate severity and 374 were classified as minor severity. There were three low severity flumethrin incidents reported to SENSOR-Pesticide (2013-2015) and three incidents were reported to NPIC (2016-2019).

The total number of flumethrin incidents reported to IDS, from 2013 to 2018, appears to be increasing over time.

The Agency will continue to monitor the incident data and if a concern is triggered, additional analysis will be conducted.

Appendix A.

Major Severity Flumethrin Incidents Reported to Main IDS from 1/1/16 to 8/27/19				
Incident Package Report	Incident Date	Location	Product Name	Incident Description
029467 - 00005	6/27/2016	SYRACUSE, NE	SERESTO LARGE DOG	An adult male was exposed to a Seresto Large Dog Collar after the collar was applied to his dog. No direct product exposure was known. Immediately after petting the dog, he developed an erythematous rash on his arms. The rash resolved a week after the collar was removed from the dog.
029467 - 00007	2/1/2016	GA	SERESTO CAT	An adult female was exposed to a Seresto Cat collar when she applied it to her cat. At an unknown date (during the same month) post exposure, she experienced numbness and pain in her arms and legs. She was diagnosed with an unspecified inflammatory neurological disease.
029467 - 00009	8/1/2016	ARKADELPHIA, AR	SERESTO LARGE DOG	A 50-year-old female was exposed to a Seresto Large Dog collar when it was placed around the neck of her dog. On an unknown date post administration, her neck tingled and turned red after she hugged her dog. The symptoms resolved after she washed her neck. The cycle of symptoms and resolution continued every time she hugged the dog.
029516 - 00002	5/1/2016		SERESTO SMALL DOG	A 74-year-old female was exposed to a Seresto Small Dog collar when she placed around her dog's neck. Six months after application of the collar, she was examined by a physician who determined she had an unspecified interstitial lung disease.
029685 - 00005	6/27/2016		SERESTO LARGE DOG	An adult female was exposed to one Seresto Large dog collar after the collar was applied to her dog and she pet the dog. No direct product exposure with the collar was known. Immediately after petting the dog, she developed an erythematous rash on her arms. Three months later, the collar was removed. Approximately a week later, her rash resolved.
029959 - 00008	10/1/2016	PEPPERELL, MA	SERESTO LARGE DOG	A 73-year-old female was exposed to a Seresto Large Dog collar on her hands when she placed it on her dog. Six month later, she experienced skin lesions inside of her nose. Three months later, she removed the collar from the dog and the clinical sign continued but improved.
030085 - 00006	10/1/2016	BEAVER FALLS, PA	SERESTO LARGE DOG	A 37-year-old male was exposed to an unknown amount of 1 Seresto Large Dog caller when he mouthed his dog that had the collar applied on the same day. No known direct exposure to the collar. Immediately post exposure, he experienced intermittent numbing sensation on his tongue. He continued to mouth his dog and the sign continued intermittently. He removed the collar from the dog and recovered.
030303 - 00020	5/27/2017	TUNKHANNOCK, PA	SERESTO	A 58-year-old woman was exposed to 1 Seresto Cat collar and 1 Seresto large dog collar when her boyfriend applied them to the pets. Approximately one month later, she experienced ocular pain, ocular redness, blurred vision and eyelid edema. She was examined by an ocular physician who determined there was an eye infection.

030314 - 00004	5/1/2017	CHESTER, IL	SERESTO SMALL DOG	A 43-year-old male was exposed to 8 collars on his hands when he applied then to the dogs in his home. He was also exposed to the collars when four of the dogs slept in his bed each night. Approximately one-week post exposure, he developed nasal congestion, a bleeding skin lesion on his ear, ear drainage, a nasal irritation, and a throat irritation. He was examined by a physician who determined that he had a hole in the ear drum and started medication. He also removed the 8 dog collars from his dogs. The ear drainage resolved. He replaced the 8 dog collars and approximately 10 days later, his ear drainage returned.
030475 - 00002	1/1/2016	EASTLAKE, OH	SERESTO DOG (UNSPECIFIED)	An 83-year-old male was exposed to multiple Seresto Dog collars that were worn by his neighbor's dogs when he played with and pet them. An unspecified date post exposure, he developed a pruritic rash on his hands, arms, back and legs.
030589 - 00001	4/30/2017	FLEETWOOD, PA	SERESTO LARGE DOG	An adult female was exposed to two Seresto Large Dog collars when she nuzzled her dogs face to face. She developed a rash on her chin and lower eye lids. Three months later, she replaced her dogs' collars with new Seresto collars and approximately four hour later, the clinical signs worsened.
030942 - 00006	12/25/2017	IA	SERESTO (UNSPECIFIED)	A 34-year-old male was secondarily exposed to the collar when he was in the home of his parent's dog who was wearing the collar around its neck. Approximately four hours post exposure, he experienced generalized pruritus and hives on both arms. When he left the dog's residence, the clinical signs improved but continued.
031139 - 00010	6/1/2016	LILLIAN, AL	SERESTO (UNSPECIFIED)	An 84-year-old female was exposed to multiple collars when she applied them to her dog and 9 cats without wearing gloves. Sometime after exposure, she experienced a tingling sensation in her entire body, the sensation of the right side of the body being asleep and difficulty using the right arm and right hand.
031139 - 00012	5/1/2017	PLYMOUTH, MA	SERESTO DOG (UNSPECIFIED)	A 78-year-old male with asthma and allergies was exposed to a Seresto dog collar when his dog would rest against his neck. He had a tick removed from his neck and experienced a lesion and localized pruritus. The next month he experienced a lesion under his arm and localized pruritus. He was tested for Lyme disease and other tick-borne illnesses and the results were negative.
031139 - 00014	10/1/2017	ALVERTON, PA	SERESTO DOG (UNSPECIFIED)	An 80-year-old female to one dog collar. She developed a digestive tract disorder.
031139 - 00015	5/2/2018	BARNEVELD, WI	SERESTO LARGE DOG	A 67-year-old woman was exposed to 1 Seresto Large Dog collar when should would pet the dog and slept in the same bed as the dog after the collar was applied. Two days later, she experienced fatigue and heart flutter (arrhythmia).
032334 - 00009	2/15/2019	OLIVER SPRINGS, TN	SERESTO DOG (UNSPECIFIED)	On 14-Feb-2019, a 12-year-old, 130-pound boy in unknown condition, with the concomitant medical conditions of a digestive tract disorder NOS and elevated blood pressure. that was taking 15 mg of Lisinopril by mouth daily since an unknown date in 2019, was secondarily exposed to an unknown amount of a Seresto Dog (unspecified) collar that was worn by the dog in the home since approximately 14-Feb-2019, and the dog slept in the bed with the boy. It was unknown if direct contact with the collar occurred. On approximately, 15-Feb-2019, the boy experienced intermittent grand mal seizures, 1 episode of emesis that resolved approximately 5 minutes post onset and mental impairment. A toxicology blood screening

				<p>panel and other unspecified blood panel were performed and were both within normal limits. The boy continued to have intermittent seizures and was examined by a pediatrician on emergency. Magnetic Resonance Imaging testing was performed of the brain with the results within normal limits. Approximately 12 hours post onset, the boy recovered. It was unknown if treatments were performed. The boy remained hospitalized for observation. On 19-Feb-2019, the boy was released from the hospital. On 26-Jun-2019, the boy had a follow up exam performed with a pediatric neurologist. An electroencephalogram was performed and showed normal brain activity .</p>
030787 - 00003	5/1/2017	TUCKERTON, NJ	SERESTO LARGE DOG	<p>In approximately May 2017, an adult female was exposed to a Seresto Large Dog collar when she placed it on her dog. Sometime after that in May 2017, the she exhibited an unspecified eye disorder. She was examined by 5 different physicians and an allergy specialist. It was determined that she had an allergy. No known treatments were provided and the clinical signs continued. In Dec 2017, the individual removed the collar from the dog. The clinical signs continued.</p>
030787 - 00006	6/1/2017	HARRISBURG, PA	SERESTO DOG (UNSPECIFIED)	<p>A 68 year old female with concomitant medical conditions of arthritis, osteoarthritis of the hand, carpal tunnel syndrome, a chronic renal disorder NOS, bile duct disorder NOS, gastric esophageal reflux disease (gastric irritation), heartburn, hypothyroidism, hypertension, osteoporosis (bone and joint disorder NOS), atrial fibrillation, pancreatic lesion (pancreas disorder), stenosing tenosynovitis/trigger finger (tendon injury), vitamin D deficiency, Fuchs corneal dystrophy (eye disorder NOS), corneal ulcer (corneal disorder NOS), diplopia esotropia (diplopia). posterior capsule opacification (eye disorder NOS), peripheral vascular disorder, anterior basement membrane dystrophy (eye disorder NOS) and abducens (6th) nerve palsy (cranial nerve disorder), was exposed to 1 Seresto Large Dog collar while the dog slept with her each night.</p> <p>Sometime post exposure she experienced double vision. She was examined by multiple physicians (neurologist, primary care physician, prism eye doctor and a general eye doctor) and had multiple tests performed (MRI, fluorescein, various ocular tests, CT scan and bloodwork). No abnormalities were found.</p> <p>In June 2017, the individual experienced headaches and one eye was unable to move (eye disorder NOS). She was examined by a physician, hospitalized for 3 days, and administered an unspecified dose of intravenous fluids. It was determined by physicians that the woman had an unspecified nerve palsy (cranial nerve disorder).</p> <p>Sometime after that she removed the collar from the dog. Sometime later she replaced the collar on her dog and her clinical signs worsened.</p>

Appendix B.

Flumethrin Incidents Reported SENSOR-Pesticide from 2013-2015			
Year	State	Severity	Incident Description
2013	North Carolina	Low	An adult woman was exposed to the collar when it was applied to her dog. She experienced a rash.
Not Available	New York	Low	The case was exposed to the collar when she 1) slept with dogs while the dogs were wearing their collar, 2) exposed to collar while trying to restrain dogs, and 3) placed collar on her bare skin (stomach). She experienced rhinitis, urticaria, pruritus, erythema, eye irritation, conjunctivitis, nasal irritation and nasal discharge, and ocular irritation
2013	New York	Low	A veterinarian applied the collar to the case's dog. The collar accidentally broke open on the case's hands. She experienced nausea, blurred vision, and heart palpitations

US EPA Office of Pesticide Programs Incident Data System

Total Rows Returned : 48

Aggregate Incident Summary Report by Product

Report Date & Time : 06/16/2020 2:46:00 PM GMT

Reg No. Selected :	011556-00155	
Product Name:	All	
Exposure Severity Code :	All	Reporting Date Range: 01/01/2012 To 06/16/2020

Package and Seq. #	Full Product Reg. #	Product Name	Form.	Total Inc.	H D	H E	D A	D B	D C D E	D C	D D	D E	W B	P B	O N T	G B	G C	D W B	D W C	G W B	G W C	S W B	S W C	P D B	P D C
024671-00008	011556-00155	SERESTO CAT	Impregnated Materials	10	0	0	0	0	0	0	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0
024968-00005	011556-00155	SERESTO LARGE DOG	Impregnated Materials	56	0	0	2	0	0	23	31	0	0	0	0	0	0	0	0	0	0	0	0	0	0
025109-00007	011556-00155	SERESTO	Impregnated Materials	141	2	0	6	0	0	32	101	0	0	0	0	0	0	0	0	0	0	0	0	0	0
025472-00010	011556-00155	SERESTO	Impregnated Materials	944	25	0	19	9	0	222	669	0	0	0	0	0	0	0	0	0	0	0	0	0	0
025767-00009	011556-00155	SERESTO	Impregnated Materials	1,661	13	0	37	90	0	447	1,074	0	0	0	0	0	0	0	0	0	0	0	0	0	0
026184-00005	011556-00155	SERESTO	Impregnated Materials	1,076	15	0	23	101	0	269	668	0	0	0	0	0	0	0	0	0	0	0	0	0	0
026494-00002	011556-00155	SERESTO	Impregnated Materials	602	4	0	17	80	0	161	350	0	0	0	0	0	0	0	0	0	0	0	0	0	0
026745-00008	011556-00155	SERESTO	Impregnated Materials	1,896	25	0	29	90	0	433	1,319	0	0	0	0	0	0	0	0	0	0	0	0	0	0
027067-00012	011556-00155	SERESTO	Impregnated Materials	2,028	30	0	31	159	0	505	1,303	0	0	0	0	0	0	0	0	0	0	0	0	0	0
027348-00007	011556-00155	SERESTO	Impregnated Materials	1,301	19	0	28	98	0	315	841	0	0	0	0	0	0	0	0	0	0	0	0	0	0
027609-00005	011556-00155	SERESTO	Impregnated Materials	775	8	0	20	80	0	197	471	0	0	0	0	0	0	0	0	0	0	0	0	0	0
027876-00012	011556-00155	SERESTO	Impregnated Materials	3,265	39	0	52	133	0	747	2,296	0	0	0	0	0	0	0	0	0	0	0	0	0	0
028098-00010	011556-00155	SERESTO	Impregnated Materials	3,507	24	0	70	273	0	770	2,370	0	0	0	0	0	0	0	0	0	0	0	0	0	0
028336-00008	011556-00155	SERESTO	Impregnated Materials	2,221	15	0	49	229	0	507	1,421	0	0	0	0	0	0	0	0	0	0	0	0	0	0
028777-00004	011556-00155	SERESTO	Impregnated Materials	1,456	20	0	37	125	0	324	950	0	0	0	0	0	0	0	0	0	0	0	0	0	0
029069-00009	011556-00155	SERESTO	Impregnated Materials	4,076	33	0	69	148	0	858	2,970	0	0	0	0	0	0	0	0	0	0	0	0	0	0
029169-00002	011556-00155	SERESTO LARGE DOG	Impregnated Materials	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
029308-00008	011556-00155	SERESTO	Impregnated Materials	4,417	26	0	86	309	0	981	3,015	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Total Rows Returned : 48

Aggregate Incident Summary Report by Product

Report Date & Time : 06/16/2020 2:46:00 PM GMT

Package and Seq. #	Full Product Reg. #	Product Name	Form.	Total Inc.	H D	H E	D A	D B	D C D E	D C	D D	D E	W B	P B	O N T	G B	G C	D W B	D W C	G W B	G W C	S W B	S W C	P D B	P D C
029600-00007	011556-00155	SERESTO	Impregnated Materials	2,488	15	0	54	239	0	600	1,580	0	0	0	0	0	0	0	0	0	0	0	0	0	
029843-00005	011556-00155	SERESTO	Impregnated Materials	1,697	15	0	54	159	1,118	351	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
030205-00008	011556-00155	SERESTO	Impregnated Materials	4,101	34	0	92	208	3,767	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
030491-00009	011556-00155	SERESTO	Impregnated Materials	4,564	24	0	87	350	4,103	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
030703-00006	011556-00155	SERESTO	Impregnated Materials	3,011	21	0	86	299	2,605	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
030964-00006	011556-00155	SERESTO	Impregnated Materials	1,490	18	0	63	157	1,252	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
031245-00008	011556-00155	SERESTO	Impregnated Materials	4,381	35	0	125	226	3,995	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
031516-00012	011556-00155	SERESTO	Impregnated Materials	5,247	40	0	148	102	4,958	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
031728-00008	011556-00155	SERESTO	Impregnated Materials	3,019	24	0	81	21	2,893	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032053-00003	011556-00155	SERESTO	Impregnated Materials	1,669	25	0	70	13	1,561	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032333-00010	011556-00155	SERESTO	Impregnated Materials	4,651	44	0	151	30	4,426	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032632-00008	011556-00155	SERESTO	Impregnated Materials	31	2	0	2	0	27	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032632-00009	011556-00155	SERESTO	Impregnated Materials	1,157	7	0	14	2	1,134	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032632-00010	011556-00155	SERESTO	Impregnated Materials	168	4	0	8	2	154	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032632-00011	011556-00155	SERESTO	Impregnated Materials	2,511	10	0	24	14	2,463	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032632-00012	011556-00155	SERESTO	Impregnated Materials	3	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032632-00013	011556-00155	SERESTO	Impregnated Materials	1,476	6	0	4	5	1,461	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032924-00004	011556-00155	SERESTO	Impregnated Materials	14	2	0	0	0	12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032924-00005	011556-00155	SERESTO	Impregnated Materials	668	5	0	12	3	648	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032924-00006	011556-00155	SERESTO	Impregnated Materials	117	5	0	4	0	108	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032924-00007	011556-00155	SERESTO	Impregnated Materials	1,231	11	0	9	3	1,208	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

US EPA Office of Pesticide Programs Incident Data System

Total Rows Returned : 48

Aggregate Incident Summary Report by Product

Report Date & Time : 06/16/2020 2:46:00 PM GMT

Package and Seq. #	Full Product Reg. #	Product Name	Form.	Total Inc.	H D	H E	D A	D B	D C D E	D C	D D	D E	W B	P B	O N T	G B	G C	D W B	D W C	G W B	G W C	S W B	S W C	P D B	P D C
032924-00008	011556-00155	SERESTO	Impregnated Materials	3	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
032924-00009	011556-00155	SERESTO	Impregnated Materials	693	6	1	12	2	672	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
033132-00006	011556-00155	SERESTO	Impregnated Materials	11	1	0	1	0	9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
033132-00007	011556-00155	SERESTO	Impregnated Materials	502	2	0	6	1	493	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
033132-00008	011556-00155	SERESTO	Impregnated Materials	80	1	0	4	1	74	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
033132-00009	011556-00155	SERESTO	Impregnated Materials	602	6	0	9	3	584	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
033132-00010	011556-00155	SERESTO	Impregnated Materials	3	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
033132-00011	011556-00155	SERESTO	Impregnated Materials	361	5	0	3	3	350	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
033132-00012	011556-00155	SERESTO CAT	Impregnated Materials	3	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Summary by Full Reg.

Full Product Reg. #	Total Inc.	HD	HE	DA	DB	DCDE	DC	DD	DE	WB	PB	ONT	GB	GC	DWB	DWC	GWB	GWC	SWB	SWC	PDB	PDC
011556-00155	75,385	666	1	1,698	3,767	40,087	7,743	21,439	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Summary by 11 Character Reg.

11 Char Reg. #	Total Inc.	HD	HE	DA	DB	DCDE	DC	DD	DE	WB	PB	ONT	GB	GC	DWB	DWC	GWB	GWC	SWB	SWC	PDB	PDC
011556-00155	75,385	666	1	1,698	3,767	40,087	7,743	21,439	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Exposure Severity Code	Description
DA	Domestic Animal - Fatality
DB	Domestic Animal - Major
DC	Domestic Animal - Moderate
DCDE	Domestic Animal - Moderate, Minor and Unknown
DD	Domestic Animal - Minor
DE	Domestic Animal - Unspecified
DWB	Drinking Water - Moderate

US EPA Office of Pesticide Programs Incident Data System

Total Rows Returned : 48

Aggregate Incident Summary Report by Product

Report Date & Time : 06/16/2020 2:46:00 PM GMT

Exposure Severity Code	Description
DWC	Drinking Water - Minor
GB	Groundwater - Moderate (with possibly mixed types of water)
GC	Groundwater - Minor (with possibly mixed types of water)
GWB	Groundwater - Moderate
GWC	Groundwater - Minor
HD	Human - Minor
HE	Human - Unspecified
ONT	Other Nontarget
PB	Plant Damage - Minor
PDB	Property Damage - Moderate
PDC	Property Damage - Minor
PL	Plant Lawn
SWB	Surface Water - Moderate
SWC	Surface Water - Minor
WB	Wildlife - Minor

Message

From: Daguillard, Robert [Daguillard.Robert@epa.gov]
Sent: 3/2/2021 5:13:04 PM
To: Overbey, Dian [Overbey.Dian@epa.gov]; OPS CSID CB [OPS_CSID_CB@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]
CC: Labbe, Ken [Labbe.Ken@epa.gov]
Subject: RE: OPS MEDIA INQUIRY : SERESTO - query from a NY Post reporter

<https://www.usatoday.com/story/news/investigations/2021/03/02/seresto-dog-cat-collars-found-harm-pets-humans-epa-records-show/4574753001/>

Best, R.

Robert Daguillard
Public Affairs Officer
U.S. Environmental Protection Agency
Washington, DC
+1 (202) 564-6618 (o)
+1 (202) 360-0476 (m)

From: Overbey, Dian <Overbey.Dian@epa.gov>
Sent: Tuesday, March 02, 2021 12:11 PM
To: Daguillard, Robert <Daguillard.Robert@epa.gov>; OPS CSID CB <OPS_CSID_CB@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>
Cc: Labbe, Ken <Labbe.Ken@epa.gov>
Subject: RE: OPS MEDIA INQUIRY : SERESTO - query from a NY Post reporter

Got it.

Dian D. Overbey
Communications Branch
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Potomac Yard S-8927
(703) 305-5018 (O)
(571) 302-0764 (OC)
(202) 460-4875 (Personal Cell)

From: Daguillard, Robert <Daguillard.Robert@epa.gov>
Sent: Tuesday, March 02, 2021 12:07 PM
To: OPS CSID CB <OPS_CSID_CB@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>
Cc: Labbe, Ken <Labbe.Ken@epa.gov>
Subject: RE: OPS MEDIA INQUIRY : SERESTO - query from a NY Post reporter

Follow-up: Inside Edition on the same issue:

We would like a statement from the EPA regarding this matter.

Additional questions are as follows:

Knowing the risks why did the EPA allow this product from going to market?
Why didn't the EPA act sooner?

Best, R.

Robert Daguillard
Public Affairs Officer
U.S. Environmental Protection Agency
Washington, DC
+1 (202) 564-6618 (o)
+1 (202) 360-0476 (m)

From: Daguillard, Robert
Sent: Tuesday, March 02, 2021 11:25 AM
To: OPS CSID CB <OPS_CSID_CB@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>
Cc: Labbe, Ken <Labbe.Ken@epa.gov>
Subject: OPS MEDIA INQUIRY : SERESTO - query from a NY Post reporter

NY POST
LISA FICKENSHER
AWAITING DDL INFO

Team, I've attached the response we sent Johnathan Hettinger of MCIR on this issue on Feb. 12. I hope it'll prove helpful. I have to say the highlighted question is the one that caught my attention, so I'm wondering if the attached will prove enough on that front. Do we need to say something a bit more forceful instead

Best, R.

Robert Daguillard
Public Affairs Officer
U.S. Environmental Protection Agency
Washington, DC
+1 (202) 564-6618 (o)
+1 (202) 360-0476 (m)

From: Lisa Fickenscher <lfickenscher@nypost.com>
Sent: Tuesday, March 02, 2021 11:06 AM
To: Press <Press@epa.gov>
Subject: query from a NY Post reporter

Hi,
I'm a business reporter for The New York Post and I'm reaching out regarding a USA Today report on Seresto flea/tick collars.

According to the report, the EPA has received thousands of complaints from pet owners about these collars, but has not warned the public about a potential problem involving the products.

Is it accurate that the EPA has received reports of 1,698 pet deaths attributed to the collars and more than 75,000 incident reports about the products and nearly 1,000 incidents of human harm?

Please advise.

Thank you,

Lisa

914-275-7121

--

LISA FICKENSCHER

RETAIL REPORTER, *New York Post*

1211 AVENUE OF THE AMERICAS, NEW YORK, NY 10036

OFFICE: (212) 930-8664

NEW YORK POST

Message

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 2/22/2018 4:36:08 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]
CC: Davis, Donna [Davis.Donna@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
Subject: RE: General

Excellent – thank you! We will confirm with OGC on **Ex. 5 AC/DP**

Best,
Catherine

From: Goodis, Michael
Sent: Thursday, February 22, 2018 11:33 AM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Davis, Donna <Davis.Donna@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: RE: General

Also...OK to grant time extensions for the premise/ant efficacy data as requested.

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

From: Goodis, Michael
Sent: Thursday, February 22, 2018 11:30 AM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Davis, Donna <Davis.Donna@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: RE: General

Catherine

Spoke with Rick this morning and he agreed with lifting the time limitation restriction for **Ex. 5 Deliberative Process (DP)** t registration provided OGC was OK with it. I think they were but please confirm if you have not yet.

Also regarding the **Ex. 5 Deliberative Process (DP)** he agreed with issuing a cancellation letter for the expired product. Registrants need to manage their own product registrations. Likewise, considering our limited resources, I am OK with discontinuing the tracking/reminders for their registrations. Your call.

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

From: Aubee, Catherine
Sent: Wednesday, February 21, 2018 8:24 AM

To: Goodis, Michael <Goodis.Michael@epa.gov>

Cc: Davis, Donna <Davis.Donna@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>

Subject: RE: General

Hi Mike, here you go:

PRIA

- RD/BPPD/OGC met on 2/15 to discuss EPA File Symbol **Ex. 5 Deliberative Process (DP)**
Ex. 5 Deliberative Process (DP) A question has been raised as to whether **Ex. 5 Deliberative Process (DP)** active ingredients (will remain in BPPD) or inert ingredients (will go to RD). A decision was not made during the meeting. RD and BPPD will have a conference call on 2/22 with the registrant to ask questions on how the product will be used and how it will be marketed. The primary internal question is how we should be handling **Ex. 5 Deliberative Process (DP)**
- Transfluthrin: waiting on HED risk assessment.

Non-PRIA

- We will have a considerable amount of non-PRIA actions (e.g., rereg) to reassign in March. Although they will be reassigned, they will be lower priority for completion given our current PRIA workload.

Efficacy

- CSPA wrote a letter to Rick on 2/9/18 indicating that they're forming an Efficacy Task Force to address the rereg data issues. A few registrants have already responded with this letter, indicating that they plan to complete the required efficacy studies after the premises guideline is finalized. Jenn and Bo are following up on uses not covered by the guideline and the submission of a general bridging argument.
 - May we proceed with accepting the extensions request until guideline completion for premises and fire ant uses?
- The presentations for the SAP will be given to the BCs/Anna for review today; they'll likely go to the DD level on March 9 for review.

Incidents

- Seresto (flumethrin); PRD, RD and HED met on 2/8 to discuss how best to handle the review of incidents for Seresto. A clear path forward was not decided upon. HED will look at the number of incidents that have been reported since their review in 2015. PRD will schedule another meeting to discuss.

Other

- Topics needed for Monthly Chemical Review mtg (3/5)
- Waiting for feedback from OD level on (1) issuing cancellation letter for expired product and (2) removing time limitation for **Ex. 5 Deliberative Process (DP)** that has satisfied its conditional data requirements

Personnel

- Request clearance to post PMF rotation and Marion Barry Summer Intern announcements (attached)
- No FTEs required, but must provide space, computer, etc.

From: Goodis, Michael

Sent: Wednesday, February 21, 2018 8:18 AM

To: Aubee, Catherine <Aubee.Catherine@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>

Cc: Davis, Donna <Davis.Donna@epa.gov>

Subject: General

Please send me your agenda items via email.

I am teleworking this morning and can be reached at **Ex. 6 PP – personal phone**

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

Message

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 2/21/2018 1:23:38 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]
CC: Davis, Donna [Davis.Donna@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
Subject: RE: General
Attachments: OPP RD IVB1 pmf_tms_agy_rotational_advertisement 02-14-2018.doc; DRAFT RD MBSYEP announcement 02-16-2018.docx

Hi Mike, here you go:

PRIA

- RD/BPPD/OGC met on 2/15 to discuss EPA File Symbol

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

A question has been raised as to whether active ingredients (will remain in BPPD) or inert ingredients (will go to RD). A decision was not made during the meeting. RD and BPPD will have a conference call on 2/22 with the registrant to ask questions on how the product will be used and how it will be marketed. The primary internal question is how we should be handling

Ex. 5 Deliberative Process (DP)

- Transfluthrin: waiting on HED risk assessment.

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Other

- Topics needed for Monthly Chemical Review mtg (3/5)
- Waiting for feedback from OD level on (1) issuing cancellation letter for expired product and (2) removing time limitation for **Ex. 5 Deliberative Process (DP)** that has satisfied its conditional data requirements

Personnel

- Request clearance to post PMF rotation and Marion Barry Summer Intern announcements (attached)
- No FTEs required, but must provide space, computer, etc.

From: Goodis, Michael

Sent: Wednesday, February 21, 2018 8:18 AM

To: Aubee, Catherine <Aubee.Catherine@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>

ED_005739A_00207036-00001

Cc: Davis, Donna <Davis.Donna@epa.gov>

Subject: General

Please send me your agenda items via email.

I am teleworking this morning and can be reached at Ex. 6 PP – personal phone

Michael L. Goodis, P.E.

Director, Registration Division (RD)

Office of Pesticide Programs (OPP)

Phone 703-308-8157

Room S7623

Message

From: Parrott, Patricia [parrott.patricia@epa.gov]
Sent: 6/20/2019 7:41:00 PM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]
CC: Davis, Donna [Davis.Donna@epa.gov]; Miller, Wynne [Miller.Wynne@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]
Subject: FW: Noteworthy Case from NPIC (Seresto collar)
Attachments: 2019_4456,4443.pdf

FYI: Dog collar incident

From: Rivera-Lupianez, Ana
Sent: Thursday, June 20, 2019 3:32 PM
To: Chen, Jonathan <Chen.Jonathan@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>; Mastrota, Nicholas <Mastrota.Nicholas@epa.gov>; Panger, Melissa <Panger.Melissa@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Rivera-Lupianez, Ana <Rivera-Lupianez.Ana@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>
Cc: Parrott, Patricia <parrott.patricia@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>; Han, Kaythi <Han.Kaythi@epa.gov>; Hopkins, Yvette <Hopkins.Yvette@epa.gov>; Lloyd, Matthew <Lloyd.Matthew@epa.gov>
Subject: FW: Noteworthy Case from NPIC (Seresto collar)

Hi,

Pet incident involving a Seresto flea collar. Please forward to interested staff.

Thanks,
Ana

Ana Rivera-Lupiañez
Pesticide Worker Safety Programs
Office of Pesticide Programs
Environmental Protection Agency
rivera-lupianez.ana@epa.gov
(703) 308-6841

From: Hughes, Cameron C <Cameron.Hughes@oregonstate.edu>
Sent: Wednesday, June 19, 2019 11:20 AM
To: Rivera-Lupianez, Ana <Rivera-Lupianez.Ana@epa.gov>
Cc: Cross, Amy S <Amy.Cross@oregonstate.edu>; Sean Ross <rossse@oregonstate.edu>
Subject: Re: Noteworthy Case from NPIC

Hi Ana,

Attached is another noteworthy case about Seresto flea collars.

Thank you,
Cameron

--

Cameron Hughes

Knowledge Management & Project Specialist
National Pesticide Information Center
Pesticide Educational Resources Collaborative
Oregon State University
310 Weniger Hall
Corvallis, OR 97331
(541) 737-6123

On Tue, Jun 18, 2019 at 2:58 PM Hughes, Cameron C <Cameron.Hughes@oregonstate.edu> wrote:

Hi Ana,

We had a sentinel report today in Idaho state. I've attached the report.

Please let us know if you have any questions,

Cam

--

Cameron Hughes
Knowledge Management & Project Specialist
National Pesticide Information Center
Pesticide Educational Resources Collaborative
Oregon State University
310 Weniger Hall
Corvallis, OR 97331
(541) 737-6123

Date: 6/14/2019

City, State: SAPPHIRE, NC

Narrative for log 4456: Caller wishing to file a report after his dog had a reaction to a Seresto flea collar, EPA registration number 11556-155 (active ingredients imidacloprid, flumethrin). Caller reported that the dog (6-year-old, 67 lb., intact male purebred Labrador) had been wearing the collar for about 9 months or a year, and then in March (three months ago) had a large seizure in their home. Caller reported that he immediately removed the collar, and about six weeks later the dog had another seizure. Caller reported that the dog is a hunting dog and is in excellent physical health. Caller reported that he has been working with his veterinarian who also suspects that the collar was the source of the seizures. Caller reported he has been detoxing the dog for a couple months now and hasn't had any further seizures. Caller reported he has seen extensive reports of reactions to this specific type of flea collar and is shocked that the EPA has not stopped it from being sold.

Discussed NPIC services, including not working for the EPA directly. Discussed NPIC incident documentation and reporting to the EPA. Discussed that reporting adverse reactions to the manufacturer is an additional method to report when incidents occur. Discussed that products are also registered at a state level and provided the State Lead Pesticide Agency as a resource for reporting his concerns regarding the availability of this product. Caller sent follow-up email, see log 4443.

Narrative for log 4443: Email Received:

Here is the web contact that will show you what a veterinarian has to say about this poisonous dog collar

I'm a relatively intelligent human being with a good education and I can't for the life of me figure out why I let my dog wear this Horrible poisonous flea collar.

As it turns out these pesticides are very potent and do have side effects such as seizures

You will see a chart in this report that shows you how many people have reported this product that should not be on the market in the first place.

This is just about money not the welfare of our beloved pets.

My dog comes from a long line of field trial champions. This animal is as fit as an animal can be. This poisonous product turned him into a quivering mass and for a while I was afraid, I was going to lose him and by the way other dogs have died from this stuff

I'd really like to get the guy on the phone that authorizes this product to be sold without any proper warnings that your pet may be turned into a giant quivering mass.



2019 REFERRAL TO EPA

LOG: 4456, 4443

Let me know if I can be of any assistance while I look for other ways to warn other people that this product is dangerous, and it should not be put anywhere on a pet containing these kinds of pesticides

Thanks for your help today I really appreciate it and best regards
[omitted]

<http://healthydogworkshop.com/why-i-dont-recommend-seresto-collars/>

Email Response:

No response necessary, sending follow up email from earlier call log 4456. Log 4443.

Message

From: Overbey, Dian [Overbey.Dian@epa.gov]
Sent: 10/14/2016 3:54:12 PM
To: Davis, Kable [Davis.Kable@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]
CC: Overstreet, Anne [overstreet.anne@epa.gov]
Subject: RE: Region 9 information sheet on Seresto Flea and Tick collars used to reduce occurrence of Rocky Mountain spotted fever on Indian reservations
Attachments: DRAFT_Seresto flea collars_100416 ddo edits (002).docx; DRAFT_Seresto flea collars_101416 ddo kd edits clean.docx

Thanks, Bo. I've made the changes you suggested. See the second attachment.

Rick, I've attached both files so that you can see the suggestions Bo made.

Dian D. Overbey
Communication Services Branch
Field and External Affairs Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Potomac Yard S-8927
(703) 305-5018

From: Davis, Kable
Sent: Wednesday, October 12, 2016 9:04 AM
To: Overbey, Dian <Overbey.Dian@epa.gov>
Subject: RE: Region 9 information sheet on Seresto Flea and Tick collars used to reduce occurrence of Rocky Mountain spotted fever on Indian reservations

Hi Dian --

I hope your day started off well. Please find attached our comments on Region 9's Seresto document.

I hope all is well.
Bo

From: Saunders, Jennifer
Sent: Thursday, October 06, 2016 12:02 PM
To: Davis, Kable <Davis.Kable@epa.gov>
Subject: FW: Region 9 information sheet on Seresto Flea and Tick collars used to reduce occurrence of Rocky Mountain spotted fever on Indian reservations

From: Overbey, Dian
Sent: Thursday, October 06, 2016 11:58 AM
To: Jennings, Susan <Jennings.Susan@epa.gov>; Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: Region 9 information sheet on Seresto Flea and Tick collars used to reduce occurrence of Rocky Mountain spotted fever on Indian reservations

Attached is an information sheet developed by Region 9 that deals with RMSF and the use of Seresto flea and tick collars. CDC had initiated a program to put Seresto collars on dogs after an outbreak of the tick-bourne disease in Indian Country in Arizona. Region 9 is thinking of distributing this as a Region 9 information sheet that can either stand alone or be attached to tribal newsletters. Patti TenBrook has asked for feedback from headquarters. We'd appreciate your comments by next Wednesday, October 12.

Thanks,

Dian D. Overbey
Communication Services Branch
Field and External Affairs Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Potomac Yard S-8927
(703) 305-5018

Message

From: Overbey, Dian [Overbey.Dian@epa.gov]
Sent: 10/18/2016 12:58:04 PM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]; TenBrook, Patti [TenBrook.Patti@epa.gov]
CC: Overstreet, Anne [overstreet.anne@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]
Subject: RE: Questions about Seresto collars
Attachments: DRAFT_Seresto flea collars_101816_with PT suggestions.docx

Thanks so much, Rick. I made the corrections.

Patti, good to go unless you want to wait for Bo Davis's input. He'll be back in the office on Thursday.

Dian

From: Keigwin, Richard
Sent: Tuesday, October 18, 2016 7:45 AM
To: Overbey, Dian <Overbey.Dian@epa.gov>
Cc: TenBrook, Patti <TenBrook.Patti@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Bacon, Laura <Bacon.Laura@epa.gov>
Subject: RE: Questions about Seresto collars

Thanks. Two comments:

-
- # Ex. 5 Deliberative Process (DP)

From: Overbey, Dian
Sent: Monday, October 17, 2016 10:19 AM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: TenBrook, Patti <TenBrook.Patti@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Bacon, Laura <Bacon.Laura@epa.gov>
Subject: RE: Questions about Seresto collars

Thank, Rick. Tonight is fine.

Dian

From: Keigwin, Richard
Sent: Monday, October 17, 2016 10:05 AM
To: Overbey, Dian <Overbey.Dian@epa.gov>
Cc: TenBrook, Patti <TenBrook.Patti@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Bacon, Laura <Bacon.Laura@epa.gov>
Subject: RE: Questions about Seresto collars

I'm not going to be able to look at this until this evening. My apologies.

From: Overbey, Dian
Sent: Monday, October 17, 2016 9:54 AM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: TenBrook, Patti <TenBrook.Patti@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Bacon, Laura <Bacon.Laura@epa.gov>
Subject: FW: Questions about Seresto collars

Hi. Patti had some concerns that I have tried to address. See her suggestions below the new draft and the highlighting within the draft.

WEIGHING RISKS TO CHILDREN FROM DOGS WEARING SERESTO™ COLLARS

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Further information about pesticides and pets is available at <https://www.epa.gov/pets>.

Report adverse incidents caused by use of pest collars at <https://www.epa.gov/pesticide-incidents/report-pesticide-exposure-incidents-affecting-pets-or-domestic-animals>.

For questions about information in this bulletin, contact Patti TenBrook in the U.S. EPA Region 9 Pesticides Office at 415-947-4223.

¹http://www.cdc.gov/nceh/ehs/News/Features/2014/rmsf_rodeo.html

²https://www.epa.gov/sites/production/files/2016-08/documents/vector-borne_diseases_workshop_presentations_epa_region_9_2016-08-08.pdf, pp 135 ff

³<http://www.cdc.gov/rmsf/symptoms/index.html>

⁴<http://www.cdc.gov/rmsf/index.html>

From: TenBrook, Patti

Sent: Friday, October 14, 2016 4:22 PM

To: Overbey, Dian <Overbey.Dian@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>

Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>

Subject: RE: Questions about Seresto collars

I think it's close. Couple of things that I'm struggling with.

1)

2)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

3) To address Bo's comment about mentioning other collars, I would suggest this:

Ex. 5 Deliberative Process (DP)

My suggested words may not be quite right, but I hope we can work through my concerns. Can we find a time to talk next week?

Regards,
Patti

Patti L. TenBrook, Ph.D.
Manager, Pesticides Section
Land Division
U.S. EPA Region 9, LND-2-2
75 Hawthorne St.
San Francisco, CA 94105
415-947-4223

From: Overbey, Dian
Sent: Friday, October 14, 2016 12:23 PM
To: TenBrook, Patti <TenBrook.Patti@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>
Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>
Subject: RE: Questions about Seresto collars

Thanks for calling my attention to that, Patti. I added the sentence in the paragraph before. Forgot to delete that comment. I've attached the track changes version here so that you can get a better fix on what was changed. A few changes were made after I took track changes off.

Best,
Dian

From: TenBrook, Patti
Sent: Friday, October 14, 2016 3:08 PM
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Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>
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Sent: 10/17/2016 2:18:57 PM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]
CC: TenBrook, Patti [TenBrook.Patti@epa.gov]; Overstreet, Anne [overstreet.anne@epa.gov]; Bacon, Laura [Bacon.Laura@epa.gov]
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Message

From: Keigwin, Richard [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=151BAABB6A2246A3A312F12A706C0A05-RICHARD P KEIGWIN JR]
Sent: 10/18/2016 11:45:09 AM
To: Overbey, Dian [Overbey.Dian@epa.gov]
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If you could take a quick look and let me know if anything needs further editing, that would be super.

Thanks for your help.

Regards,

Patti

Patti L. TenBrook, Ph.D.
Manager, Pesticides Section
Land Division
U.S. EPA Region 9, LND-2-2
75 Hawthorne St.
San Francisco, CA 94105
415-947-4223

From: Overstreet, Anne

Sent: Tuesday, September 6, 2016 10:17 AM

To: TenBrook, Patti <TenBrook.Patti@epa.gov>

Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>; Overbey, Dian <Overbey.Dian@epa.gov>

Subject: RE: Questions about Seresto collars

Hi Patti, I've looked over the attachment related to the Seresto flea collars and I've included Debby Sisco who could also provide some additional thoughts.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Also, we would like to highlight where the public can go for additional information, including <https://www.epa.gov/pets> and reporting any adverse incidents by pet owners to: <https://www.epa.gov/pesticide-incidents/report-pesticide-exposure-incidents-affecting-pets-or-domestic-animals>

Debby, are you OK with the language in the attachment?

Anne

From: TenBrook, Patti

Sent: Thursday, September 01, 2016 3:28 PM

To: Overstreet, Anne <overstreet.anne@epa.gov>

Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>; Overbey, Dian <Overbey.Dian@epa.gov>

Subject: RE: Questions about Seresto collars

Anne,

Based on the information you sent, and information from CDC, I have drafted this information sheet. I'm trying to be straightforward about what EPA did and did not assess in terms of human exposure and potential effects. The sentence I highlighted in yellow is a concept I want to include, but I don't think I have the right language.

I would appreciate your expert communicator eyes on this. I have been tasked with having information back to tribes sometime in September. I will be out next week, but hope you might have a chance to review and comment within a few weeks.

As I mentioned, I've not heard of any specific incidents with this collar, but would be interested in what Kable is hearing about. Is he hearing reports of incidents affecting pets or people or both?

Regards,
Patti

Patti L. TenBrook, Ph.D.
Manager, Pesticides Section
Land Division
U.S. EPA Region 9, LND-2-2
75 Hawthorne St.
San Francisco, CA 94105
415-947-4223

From: Overstreet, Anne

Sent: Tuesday, August 30, 2016 4:51 AM

To: TenBrook, Patti <TenBrook.Patti@epa.gov>

Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>

Subject: RE: Questions about Seresto collars

Patti, there was a risk assessment that looked at exposure to children. We'll look for some additional information to send you. We have received incident data around the use of this collar which is projected to last 8-10 months when placed on the dog.

Dian, please work with Kable Davis in RD to obtain information related to the registration of the Seresto collar – he now manages this one. I didn't see a combination risk assessment in the docket for imidacloprid and Flumethrin. I did leave a message for Kable this morning asking for the risk assessment.

Anne

From: TenBrook, Patti

Sent: Monday, August 29, 2016 4:46 PM

To: Overstreet, Anne <overstreet.anne@epa.gov>

Subject: Questions about Seresto collars

Hi Anne,

We had a vector-borne diseases workshop for our tribes here in Region 9 in early August. One of the topics was Rocky Mountain Spotted Fever (RMSF) and the use of Seresto collars for tick control.

Label is here: https://www3.epa.gov/pesticides/chem_search/ppls/011556-00155-20140403.pdf

There were a lot of questions about the safety of these collars for children, whether they might put one in their mouth, or cuddle up to a dog who is wearing one. There is a choking hazard warning on the label, but nothing about potential pesticide exposure for children. Do you have any information on this? I can't find anything on this combination of active ingredients, or on the time-release action. Is the pesticide absorbed into the blood and then ingested by insects? Or does it work by spreading over the animal's coat and killing on contact?

Do we have any outreach materials on pet collars in general, or this collar in particular? I have found a lot of information about spot-on products, but not really anything on collars. I can't even find anything from NPIC.

I'd like to report back to the tribes with some perspective about relative risks of collars vs. spot-ons or other treatments vs. disease.

Regards,
Patti

Patti L. TenBrook, Ph.D.
Manager, Pesticides Section
Land Division
U.S. EPA Region 9, LND-2-2
75 Hawthorne St.
San Francisco, CA 94105
415-947-4223

Message

From: Keigwin, Richard [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=151BAABB6A2246A3A312F12A706C0A05-RICHARD P KEIGWIN JR]
Sent: 10/17/2016 2:04:54 PM
To: Overbey, Dian [Overbey.Dian@epa.gov]
CC: TenBrook, Patti [TenBrook.Patti@epa.gov]; Overstreet, Anne [overstreet.anne@epa.gov]; Bacon, Laura [Bacon.Laura@epa.gov]
Subject: RE: Questions about Seresto collars

I'm not going to be able to look at this until this evening. My apologies.

From: Overbey, Dian
Sent: Monday, October 17, 2016 9:54 AM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: TenBrook, Patti <TenBrook.Patti@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Bacon, Laura <Bacon.Laura@epa.gov>
Subject: FW: Questions about Seresto collars

Hi. Patti had some concerns that I have tried to address. See her suggestions below the new draft and the highlighting within the draft.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Further information about pesticides and pets is available at <https://www.epa.gov/pets>.

Report adverse incidents caused by use of pest collars at <https://www.epa.gov/pesticide-incidents/report-pesticide-exposure-incidents-affecting-pets-or-domestic-animals>.

For questions about information in this bulletin, contact Patti TenBrook in the U.S. EPA Region 9 Pesticides Office at 415-947-4223.

¹http://www.cdc.gov/nceh/ehs/News/Features/2014/rmsf_rodeo.html

²https://www.epa.gov/sites/production/files/2016-08/documents/vector-borne_diseases_workshop_presentations_epa_region_9_2016-08-08.pdf, pp 135 ff

³<http://www.cdc.gov/rmsf/symptoms/index.html>

⁴<http://www.cdc.gov/rmsf/index.html>

From: TenBrook, Patti

Sent: Friday, October 14, 2016 4:22 PM

To: Overbey, Dian <Overbey.Dian@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>

Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>

Subject: RE: Questions about Seresto collars

I think it's close. Couple of things that I'm struggling with.

1)

2)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

3) To address Bo's comment about mentioning other collars, I would suggest this:

Ex. 5 Deliberative Process (DP)

My suggested words may not be quite right, but I hope we can work through my concerns. Can we find a time to talk next week?

Regards,
Patti

Patti L. TenBrook, Ph.D.
Manager, Pesticides Section
Land Division
U.S. EPA Region 9, LND-2-2
75 Hawthorne St.
San Francisco, CA 94105
415-947-4223

From: Overbey, Dian
Sent: Friday, October 14, 2016 12:23 PM
To: TenBrook, Patti <TenBrook.Patti@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>
Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>
Subject: RE: Questions about Seresto collars

Thanks for calling my attention to that, Patti. I added the sentence in the paragraph before. Forgot to delete that comment. I've attached the track changes version here so that you can get a better fix on what was changed. A few changes were made after I took track changes off.

Best,
Dian

From: TenBrook, Patti
Sent: Friday, October 14, 2016 3:08 PM
To: Overbey, Dian <Overbey.Dian@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>
Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>
Subject: RE: Questions about Seresto collars

Thank you so much, Dian and all. Just to be sure I have the right document.... I only see one comment. I will add a sentence, as suggested. Was that really all?

Regards,
Patti

Patti L. TenBrook, Ph.D.
Manager, Pesticides Section
Land Division
U.S. EPA Region 9, LND-2-2
75 Hawthorne St.
San Francisco, CA 94105
415-947-4223

From: Overbey, Dian
Sent: Friday, October 14, 2016 11:51 AM
To: TenBrook, Patti <TenBrook.Patti@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>
Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>
Subject: RE: Questions about Seresto collars

Hi Patti,

Here are our edits on RMSP and Seresto collar sheet. It has been reviewed by the Registration Division, the Health Effects Division and Rick Keigwin. Let me know if you have any questions.

Dian D. Overbey
Communication Services Branch
Field and External Affairs Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Potomac Yard S-8927
(703) 305-5018

From: TenBrook, Patti
Sent: Tuesday, October 04, 2016 10:16 AM
To: Overstreet, Anne <overstreet.anne@epa.gov>
Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>; Overbey, Dian <Overbey.Dian@epa.gov>
Subject: RE: Questions about Seresto collars

Anne, Colleen, Dian,

We're trying to move this along. Bill Glenn in our Office of Public Affairs has reviewed this version.

Our plan is to distribute this as a Region 9 information sheet that can either stand alone, or be attached to a tribal newsletter.

It would be great if we could have this ready for our October 24 Regional Tribal Operations Committee meeting, but that may be optimistic. I hope you be might able to send any comments by October 14.

Thanks for the help you've provided already.

Regards,
Patti

Patti L. TenBrook, Ph.D.
Manager, Pesticides Section
Land Division
U.S. EPA Region 9, LND-2-2
75 Hawthorne St.
San Francisco, CA 94105
415-947-4223

From: Overstreet, Anne
Sent: Monday, September 19, 2016 4:11 AM
To: TenBrook, Patti <TenBrook.Patti@epa.gov>
Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>; Overbey, Dian <Overbey.Dian@epa.gov>
Subject: RE: Questions about Seresto collars

Sure, Patti.

Dian, could you run the language by David Miller in HED? I wanted to make sure the characterization of the potential side effects is complete.

Thanks,
Anne

From: TenBrook, Patti
Sent: Friday, September 16, 2016 12:59 PM
To: Overstreet, Anne <overstreet.anne@epa.gov>
Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>; Overbey, Dian <Overbey.Dian@epa.gov>
Subject: RE: Questions about Seresto collars

Hi Anne,

I've not heard anything further from anyone, so have incorporated your suggestions. The updated version is attached. If the text is OK, I will try to include some graphics so that it is a nice 2-pager.

If you could take a quick look and let me know if anything needs further editing, that would be super.

Thanks for your help.

Regards,
Patti

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From: Overstreet, Anne
Sent: Tuesday, August 30, 2016 4:51 AM
To: TenBrook, Patti <TenBrook.Patti@epa.gov>
Cc: Keltz, Colleen <Keltz.Colleen@epa.gov>
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Patti

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Manager, Pesticides Section
Land Division
U.S. EPA Region 9, LND-2-2
75 Hawthorne St.
San Francisco, CA 94105
415-947-4223

Appointment

From: Piansay, Maria [Piansay.Maria@epa.gov]
Sent: 9/20/2016 12:00:59 PM
To: Piansay, Maria [Piansay.Maria@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Vogel, Dana [Vogel.Dana@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]
CC: Housenger, Jack [Housenger.Jack@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Knorr, Michele [Knorr.Michele@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]
Subject: FW: Flumethrin Bayer Meeting
Location: DCRoomPYS9261/Potomac-Yard-One

Start: 9/22/2016 6:00:00 PM
End: 9/22/2016 7:00:00 PM
Show Time As: Busy

-----Original Appointment-----

From: Piansay, Maria
Sent: Tuesday, September 13, 2016 2:51 PM
To: Piansay, Maria; Guilaran, Yu-Ting; Vogel, Dana; Rosenblatt, Daniel; Echeverria, Marietta; Miller, David; Rossmeisl, Colleen; Arrington, Linda; Davis, Kable; Biscoe, Melanie
Cc: Knorr, Michele; Goodis, Michael
Subject: Flumethrin Bayer Meeting
When: Thursday, September 22, 2016 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomPYS9261/Potomac-Yard-One

Meeting Agenda from Bayer

1. To discuss status and timing of the documents EPA intends to release in September regarding Flumethrin and the Flumethrin-containing products;
2. To review timing of registration review for the Flumethrin-containing products and inclusion in the pyrethroid registration review;
3. To understand references and approach in these documents to Seresto;
4. To express Bayer's perspective on potential references to Flumethrin and Seresto;
5. To understand the anticipated scope of the registration review, and the expected schedule for the conduct of the review;
6. For Bayer to understand from the Agency its intentions and next steps in this process.

Attending from Bayer will be:

- Joyce Lee, President, Commercial Operations North America, Bayer Animal Health
- Robert Zolynas, Vice President Research and Development, North America, Bayer Animal Health
- Jessica Monachello, Assistant General Counsel Bayer Animal Health
- Roger R. Martella Jr., Outside Counsel, Sidley Austin LLP

Message

From: Dennis, Allison [Dennis.Allison@epa.gov]
Sent: 2/11/2021 10:14:24 PM
To: Freedhoff, Michal [Freedhoff.Michal@epa.gov]
CC: Ozmen, Shamus [Ozmen.Shamus@epa.gov]; Diaz, Catherine [Diaz.Catherine@epa.gov]; Tyler, Tom [Tyler.Tom@epa.gov]; Richmond, Jonah [Richmond.Jonah@epa.gov]; Siciliano, CarolAnn [Siciliano.CarolAnn@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]
Subject: RE: Malloy, Ruth shared the folder "E-Binder 2-10-2021" with you.
Attachments: Response - Seresto 2-10 cleaned (003)AD.docx; Response - Seresto 2-10 ddo (002)AD.docx

Michal,

Thank you for the feedback on our drafted response to the Midwest Center for Investigative Reporting inquiry on Seresto pet collars. Attached is a revised version (both clean and track changes attached) where we tried to be more straight-forward on the first Q&A,

From: Freedhoff, Michal <Freedhoff.Michal@epa.gov>
Sent: Tuesday, February 9, 2021 7:13 PM
To: Malloy, Ruth <malloy.ruth@epa.gov>; Brown, KendraR <Brown.KendraR@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Richmond, Jonah <Richmond.Jonah@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>; Tyler, Tom <Tyler.Tom@epa.gov>
Subject: RE: Malloy, Ruth shared the folder "E-Binder 2-10-2021" with you.

Thank you

1.
2.

Ex. 5 Deliberative Process (DP)

3. Thanks for the travel form. It seems to say that it can only be faxed back for security reasons. But I don't have a fax machine at home. Does that mean I have to email it to one of you in a non-secure way so it can be faxed to them securely? ☺ fun pandemic problems.

Michal

Michal Freedhoff, Ph.D.
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Freedhoff.michal@epa.gov

From: Malloy, Ruth <malloy.ruth@epa.gov>
Sent: Tuesday, February 9, 2021 5:05 PM
To: Brown, KendraR <Brown.KendraR@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>; Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Hofmann,

Angela <Hofmann.Angela@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Richmond, Jonah <Richmond.Jonah@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>; Tyler, Tom <Tyler.Tom@epa.gov>
Subject: Malloy, Ruth shared the folder "E-Binder 2-10-2021" with you.

Here's the folder that Malloy, Ruth shared with you.



This link only works for the direct recipients of this message.



E-Binder 2-10-2021

Open



Microsoft OneDrive

Microsoft respects your privacy. To learn more, please read our [Privacy Statement](#).
Microsoft Corporation, One Microsoft Way, Redmond, WA 98052

Message

From: Messina, Edward [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95521FBF4E34496A879E364FAF7E5AA8-MESSINA, EDWARD]
Sent: 6/20/2019 7:58:03 PM
To: Rivera-Lupianez, Ana [Rivera-Lupianez.Ana@epa.gov]
Subject: RE: Noteworthy Case from NPIC (Seresto collar)
Attachments: FW: Noteworthy Case from NPIC (Seresto collar)

Thanks.

Ed Messina
Deputy Office Director (Programs)
Office of Pesticide Programs
U.S. EPA
(703) 347-0209

Message

From: Rivera-Lupianez, Ana [Rivera-Lupianez.Ana@epa.gov]
Sent: 6/20/2019 7:32:27 PM
To: Chen, Jonathan [Chen.Jonathan@epa.gov]; Crowley, Matthew [Crowley.Matthew@epa.gov]; Miller, Robert [Miller.Robert@epa.gov]; Mastrotta, Nicholas [Mastrotta.Nicholas@epa.gov]; Panger, Melissa [Panger.Melissa@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Rivera-Lupianez, Ana [Rivera-Lupianez.Ana@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Snyderman, Steven [Snyderman.Steven@epa.gov]
CC: Parrott, Patricia [parrott.patricia@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]; Han, Kaythi [Han.Kaythi@epa.gov]; Hopkins, Yvette [Hopkins.Yvette@epa.gov]; Lloyd, Matthew [Lloyd.Matthew@epa.gov]
Subject: FW: Noteworthy Case from NPIC (Seresto collar)
Attachments: 2019_4456,4443.pdf

Hi,

Pet incident involving a Seresto flea collar. Please forward to interested staff.

Thanks,
Ana

Ana Rivera-Lupiáñez
Pesticide Worker Safety Programs
Office of Pesticide Programs
Environmental Protection Agency
rivera-lupianez.ana@epa.gov
(703) 308-6841

From: Hughes, Cameron C <Cameron.Hughes@oregonstate.edu>
Sent: Wednesday, June 19, 2019 11:20 AM
To: Rivera-Lupianez, Ana <Rivera-Lupianez.Ana@epa.gov>
Cc: Cross, Amy S <Amy.Cross@oregonstate.edu>; Sean Ross <rossse@oregonstate.edu>
Subject: Re: Noteworthy Case from NPIC

Hi Ana,

Attached is another noteworthy case about Seresto flea collars.

Thank you,
Cameron

--

Cameron Hughes
Knowledge Management & Project Specialist
National Pesticide Information Center
Pesticide Educational Resources Collaborative
Oregon State University
310 Weniger Hall
Corvallis, OR 97331
(541) 737-6123

On Tue, Jun 18, 2019 at 2:58 PM Hughes, Cameron C <Cameron.Hughes@oregonstate.edu> wrote:

Hi Ana,

We had a sentinel report today in Idaho state. I've attached the report.

Please let us know if you have any questions,

Cam

--

Cameron Hughes
Knowledge Management & Project Specialist
National Pesticide Information Center
Pesticide Educational Resources Collaborative
Oregon State University
310 Weniger Hall
Corvallis, OR 97331
(541) 737-6123

Date: 6/14/2019

City, State: SAPPHIRE, NC

Narrative for log 4456: Caller wishing to file a report after his dog had a reaction to a Seresto flea collar, EPA registration number 11556-155 (active ingredients imidacloprid, flumethrin). Caller reported that the dog (6-year-old, 67 lb., intact male purebred Labrador) had been wearing the collar for about 9 months or a year, and then in March (three months ago) had a large seizure in their home. Caller reported that he immediately removed the collar, and about six weeks later the dog had another seizure. Caller reported that the dog is a hunting dog and is in excellent physical health. Caller reported that he has been working with his veterinarian who also suspects that the collar was the source of the seizures. Caller reported he has been detoxing the dog for a couple months now and hasn't had any further seizures. Caller reported he has seen extensive reports of reactions to this specific type of flea collar and is shocked that the EPA has not stopped it from being sold.

Discussed NPIC services, including not working for the EPA directly. Discussed NPIC incident documentation and reporting to the EPA. Discussed that reporting adverse reactions to the manufacturer is an additional method to report when incidents occur. Discussed that products are also registered at a state level and provided the State Lead Pesticide Agency as a resource for reporting his concerns regarding the availability of this product. Caller sent follow-up email, see log 4443.

Narrative for log 4443: Email Received:

Here is the web contact that will show you what a veterinarian has to say about this poisonous dog collar

I'm a relatively intelligent human being with a good education and I can't for the life of me figure out why I let my dog wear this Horrible poisonous flea collar.

As it turns out these pesticides are very potent and do have side effects such as seizures

You will see a chart in this report that shows you how many people have reported this product that should not be on the market in the first place.

This is just about money not the welfare of our beloved pets.

My dog comes from a long line of field trial champions. This animal is as fit as an animal can be. This poisonous product turned him into a quivering mass and for a while I was afraid, I was going to lose him and by the way other dogs have died from this stuff

I'd really like to get the guy on the phone that authorizes this product to be sold without any proper warnings that your pet may be turned into a giant quivering mass.



2019 REFERRAL TO EPA

LOG: 4456, 4443

Let me know if I can be of any assistance while I look for other ways to warn other people that this product is dangerous, and it should not be put anywhere on a pet containing these kinds of pesticides

Thanks for your help today I really appreciate it and best regards
[omitted]

<http://healthydogworkshop.com/why-i-dont-recommend-seresto-collars/>

Email Response:

No response necessary, sending follow up email from earlier call log 4456. Log 4443.

Message

From: Shuler, Jamey [Shuler.Jamey@epa.gov]
Sent: 1/16/2020 12:17:16 PM
To: Miller, Robert [Miller.Robert@epa.gov]
CC: Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]
Subject: RE: Flumethrin + Imidacloprid (Seresto)

Hi Bob,

Great meeting yesterday! Per our conversation, I am more than available today to continue our discussion.

Best Regards,

Jamey Shuler
Environmental Protection Specialist
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-8036
Shuler.Jamey@epa.gov

From: Shuler, Jamey
Sent: Tuesday, January 14, 2020 7:52 AM
To: Miller, Robert <Miller.Robert@epa.gov>
Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: Flumethrin + Imidacloprid (Seresto)

Hi Bob,

Tomorrow works well with me. Send me an invite for any time. We'll make it happen. Thank you!

Best Regards,

Jamey Shuler
Environmental Protection Specialist
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-8036
Shuler.Jamey@epa.gov

From: Miller, Robert <Miller.Robert@epa.gov>
Sent: Tuesday, January 14, 2020 7:35 AM
To: Shuler, Jamey <Shuler.Jamey@epa.gov>
Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: Flumethrin + Imidacloprid (Seresto)

Hi Jamie,

I am more than pleased to help to you with Seresto aggregate incident data. Today is not a good day for me to meet. How about tomorrow?

Bob

Robert A. Miller
6(a)(2) Coordinator
Information Technology and Resource Management Division
EPA Office of Pesticide Programs
Mail Code 7508P
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W., Washington D.C.

(703) 347-8012
miller.robert@epa.gov

From: Shuler, Jamey <Shuler.Jamey@epa.gov>
Sent: Tuesday, January 14, 2020 7:03 AM
To: Miller, Robert <Miller.Robert@epa.gov>
Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: Flumethrin + Imidacloprid (Seresto)

Hi Bob,

I am in the process of aggregating data for the Seresto (Flumethrin + Imidacloprid) product's incidents and supportive actions that may reduce risk and adverse effects towards those particular incidents. Along with this task, I am to provide a white paper to managerial staff that highlight all mentioned. When given a chance, I would love to meet with you and go over things. I have included my PM (Jackie Herrick), as she will be monitoring my progress and be involved heavily in this process.

Best Regards,

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Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-8036
Shuler.Jamey@epa.gov

Message

From: Shuler, Jamey [Shuler.Jamey@epa.gov]
Sent: 1/15/2020 1:42:49 PM
To: Miller, Robert [Miller.Robert@epa.gov]
Subject: RE: Flumethrin + Imidacloprid (Seresto)

Hi Bob,

Perfect! Thank you so much.

Best Regards,

Jamey Shuler
Environmental Protection Specialist
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-8036
Shuler.Jamey@epa.gov

From: Miller, Robert <Miller.Robert@epa.gov>
Sent: Wednesday, January 15, 2020 8:42 AM
To: Shuler, Jamey <Shuler.Jamey@epa.gov>
Subject: RE: Flumethrin + Imidacloprid (Seresto)

Hi Jamey,

Yes, we can reschedule. I'll check the calendar for another time.

Bob

Robert A. Miller
6(a)(2) Coordinator
Information Technology and Resource Management Division
EPA Office of Pesticide Programs
Mail Code 7508P
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W., Washington D.C.

(703) 347-8012
miller.robert@epa.gov

From: Shuler, Jamey <Shuler.Jamey@epa.gov>
Sent: Wednesday, January 15, 2020 8:39 AM
To: Miller, Robert <Miller.Robert@epa.gov>
Subject: RE: Flumethrin + Imidacloprid (Seresto)

Hi Bob,

Could we reschedule? I just read an email from my Division Chief - Catherine Aubee, instructing me to represent IVB1 in a managerial meeting today. That meeting is from 9:30am – 11am. Anytime after that, I am available!

Best Regards,

Jamey Shuler
Environmental Protection Specialist
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-8036
Shuler.Jamey@epa.gov

From: Shuler, Jamey
Sent: Tuesday, January 14, 2020 7:52 AM
To: Miller, Robert <Miller.Robert@epa.gov>
Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: Flumethrin + Imidacloprid (Seresto)

Hi Bob,

Tomorrow works well with me. Send me an invite for any time. We'll make it happen. Thank you!

Best Regards,

Jamey Shuler
Environmental Protection Specialist
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-8036
Shuler.Jamey@epa.gov

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Sent: Tuesday, January 14, 2020 7:35 AM
To: Shuler, Jamey <Shuler.Jamey@epa.gov>
Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: Flumethrin + Imidacloprid (Seresto)

Hi Jamie,

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Bob

Robert A. Miller
6(a)(2) Coordinator

Information Technology and Resource Management Division
EPA Office of Pesticide Programs
Mail Code 7508P
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W., Washington D.C.

(703) 347-8012
miller.robert@epa.gov

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Best Regards,

Jamey Shuler
Environmental Protection Specialist
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-8036
Shuler.Jamey@epa.gov

Message

From: Borges-Silva, Quentin [Borges-Silva.Quentin@epa.gov]
Sent: 9/19/2019 6:34:42 PM
To: Miller, Robert [Miller.Robert@epa.gov]
Subject: RE: human incidents involving Seresto collars

Ex. 5 Deliberative Process (DP)

Thanks for the info about no human reports of life-threatening allergic reactions. I'll pass that on.

Quentin Borges-Silva
EPA's Office of Pesticide Programs
"Protecting Human Health & the Environment"

From: Miller, Robert <Miller.Robert@epa.gov>
Sent: Thursday, September 19, 2019 2:07 PM
To: Borges-Silva, Quentin <Borges-Silva.Quentin@epa.gov>
Subject: RE: human incidents involving Seresto collars

Hi Quentin,

Ex. 5 Deliberative Process (DP)

Bob

Robert A. Miller
6(a)(2) Coordinator
Information Technology and Resource Management Division
EPA Office of Pesticide Programs
Mail Code 7508P
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W., Washington D.C.

(703) 347-8012
miller.robert@epa.gov

From: Borges-Silva, Quentin <Borges-Silva.Quentin@epa.gov>
Sent: Thursday, September 19, 2019 9:11 AM
To: Miller, Robert <Miller.Robert@epa.gov>
Subject: human incidents involving Seresto collars

Hi Bob.

I got a human incident report in the pesticidequestions@epa.gov inbox that I'll be forwarding to you shortly. But in formulating the response, I'm wondering if you've received reports of reactions in people, including anaphylactic shock, respiratory effects or nerve damage, associated with Seresto collars? Flumethrin and imidacloprid are the AIs.

Thanks,

Quentin Borges-Silva

EPA's Office of Pesticide Programs

"Protecting Human Health & the Environment"

Message

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 6/26/2019 2:36:57 PM
To: Miller, Robert [Miller.Robert@epa.gov]; Mastrota, Nicholas [Mastrota.Nicholas@epa.gov]; McFarley, Heather [McFarley.Heather@epa.gov]; Fletcher, Rachel [fletcher.rachel@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Snyderman, Steven [Snyderman.Steven@epa.gov]; Jones, Ricardo [Jones.Ricardo@epa.gov]; Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]; Eagle, Venus [Eagle.Venus@epa.gov]; Laws, Meredith [Laws.Meredith@epa.gov]
CC: Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Smith, Kimberly [Smith.Kimberly@epa.gov]
Subject: RE: New Tier 2 Incident: flumethrin, imidacloprid

Thank you – I will set something up. I mostly want to better understand the parameters of the 6(a)(2) reporting and we can go from there.

Please let me know if anyone else should be invited.

Cheers,
Catherine

From: Miller, Robert
Sent: Wednesday, June 26, 2019 10:36 AM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>; Mastrota, Nicholas <Mastrota.Nicholas@epa.gov>; McFarley, Heather <McFarley.Heather@epa.gov>; Fletcher, Rachel <fletcher.rachel@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>
Cc: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Smith, Kimberly <Smith.Kimberly@epa.gov>
Subject: RE: New Tier 2 Incident: flumethrin, imidacloprid

Hi Catherine,

I'm more than willing to help if I can. Enhanced pet reports go to RD without me ever seeing them, but I am willing to try to identify potential improvements.

Bob

Robert A. Miller
6(a)(2) Coordinator
Information Technology and Resource Management Division
EPA Office of Pesticide Programs
Mail Code 7508P
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W., Washington D.C.

(703) 347-8012
miller.robert@epa.gov

From: Aubee, Catherine
Sent: Wednesday, June 26, 2019 9:40 AM

To: Miller, Robert <Miller.Robert@epa.gov>; Mastrota, Nicholas <Mastrota.Nicholas@epa.gov>; McFarley, Heather <McFarley.Heather@epa.gov>; Fletcher, Rachel <fletcher.rachel@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>
Cc: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Smith, Kimberly <Smith.Kimberly@epa.gov>
Subject: RE: New Tier 2 Incident: flumethrin, imidacloprid

Hi Bob,

Thank you for providing these summary reports.

On a separate note, I sent you a message previously asking to chat about 6(a)(2) versus enhanced reporting for pet products, with the aim of identifying potential process improvements/opportunities to align as we continue to standardize the enhanced reporting process.

If you are unavailable to meet or think this is out of your lane, please let me know would be best to discuss this with.

Best,
Catherine
Chief, OPP RD IVB1

From: Miller, Robert
Sent: Wednesday, June 26, 2019 9:16 AM
To: Mastrota, Nicholas <Mastrota.Nicholas@epa.gov>; McFarley, Heather <McFarley.Heather@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Fletcher, Rachel <fletcher.rachel@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>
Cc: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Smith, Kimberly <Smith.Kimberly@epa.gov>
Subject: RE: New Tier 2 Incident: flumethrin, imidacloprid

Hi All,

The other day I queried both aggregate and individual Seresto incidents in the Incident Data System (see attachments).

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Bob

Robert A. Miller
6(a)(2) Coordinator
Information Technology and Resource Management Division
EPA Office of Pesticide Programs
Mail Code 7508P
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W., Washington D.C.

(703) 347-8012

miller.robert@epa.gov

From: Mastrota, Nicholas

Sent: Wednesday, June 26, 2019 8:56 AM

To: McFarley, Heather <McFarley.Heather@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Fletcher, Rachel <fletcher.rachel@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>

Cc: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>

Subject: RE: New Tier 2 Incident: flumethrin, imidacloprid

Catherine et al.,

The reporting of the Seresto and other incidents for pet products in this aggregated format is the result of our current 6a2 regulations which allows registrants to report of all incidents to domesticated animals, regardless of severity, to be reported in aggregated form without any narrative of individual incidents. Several years ago there was an effort in OPP to update the regulations to get better reporting, but that effort seemed to have died out a couple of years ago. In the meantime, risk managers should know that the 6a2 regulations do allow request of additional information from registrants on incidents that are reported in aggregate form for pesticides that are currently under regulatory review.

Nick

From: McFarley, Heather

Sent: Tuesday, June 25, 2019 3:58 PM

To: Aubee, Catherine <Aubee.Catherine@epa.gov>; OPP Incidents Screening <Opp_Incidents_Screening@epa.gov>; Fletcher, Rachel <fletcher.rachel@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>

Cc: Mastrota, Nicholas <Mastrota.Nicholas@epa.gov>

Subject: RE: New Tier 2 Incident: flumethrin, imidacloprid

Hello Catherine,

I hope you are well.

The incident report you received is the tracking of all the incidents related to the identified product (Seresto) and active ingredients (flumethrin-imidacloprid) over the given time period (Jan 1 – Mar 31, 2019). Attached is a reference that defines the definitions of the severity category (see pg 24). There is no additional narrative associated with the aggregate report. Let me know if you have any additional questions/concerns. Thank you.

Have a good day,
Heather

From: Aubee, Catherine

Sent: Tuesday, June 25, 2019 1:22 PM

To: McFarley, Heather <McFarley.Heather@epa.gov>; OPP Incidents Screening <Opp_Incidents_Screening@epa.gov>; Fletcher, Rachel <fletcher.rachel@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>

Subject: RE: New Tier 2 Incident: flumethrin, imidacloprid

Hi Heather *et al.*,

Is there a narrative incident report associated with this item? I only see the aggregate numbers in the attachment.

Best,
Catherine
Chief, OPP RD IVB1

From: McFarley, Heather

Sent: Friday, May 31, 2019 4:02 PM

To: OPP Incidents Screening <Opp_Incidents_Screening@epa.gov>; Fletcher, Rachel <fletcher.rachel@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>

Subject: RE: New Tier 2 Incident: flumethrin, imidacloprid

Please disregard previous incident. Attached is the incident for flumethrin and imidacloprid. Thank you.

Have a good weekend,
Heather

From: OPP Incidents Screening

Sent: Friday, May 31, 2019 4:00 PM

To: Fletcher, Rachel <fletcher.rachel@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>

Subject: New Tier 2 Incident: flumethrin, imidacloprid

Good afternoon,

Attached is an incident related to an AI(s) you manage. The incident was labeled a Tier 2 incident by the OPP Incident Screening Team (IST). Tier 2 indicates that the incident is NOT high-priority and generally does not require immediate action, thus risk managers are notified of Tier 2 incidents primarily as an FYI, and the incidents can be addressed in the next registration/registration review action. Please let us know if you have any questions or comments.

Have a good day,

Heather McFarley
Secretary, Incident Screening Team

Message

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 6/26/2019 1:06:58 PM
To: Mastrota, Nicholas [Mastrota.Nicholas@epa.gov]
CC: McFarley, Heather [McFarley.Heather@epa.gov]; Fletcher, Rachel [fletcher.rachel@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Snyderman, Steven [Snyderman.Steven@epa.gov]; Jones, Ricardo [Jones.Ricardo@epa.gov]; Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]; Eagle, Venus [Eagle.Venus@epa.gov]; Laws, Meredith [Laws.Meredith@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Miller, Robert [Miller.Robert@epa.gov]
Subject: Re: New Tier 2 Incident: flumethrin, imidacloprid

Thank you, Nick. I understand what the aggregate summaries are. I was confused by the wording of the transmittal email and wanted to ensure we were not missing something.

All the best,
Catherine

On Jun 26, 2019, at 8:56 AM, Mastrota, Nicholas <Mastrota.Nicholas@epa.gov> wrote:

Catherine et al.,

The reporting of the Seresto and other incidents for pet products in this aggregated format is the result of our current 6a2 regulations which allows registrants to report of all incidents to domesticated animals, regardless of severity, to be reported in aggregated form without any narrative of individual incidents. Several years ago there was an effort in OPP to update the regulations to get better reporting, but that effort seemed to have died out a couple of years ago. In the meantime, risk managers should know that the 6a2 regulations do allow request of additional information from registrants on incidents that are reported in aggregate form for pesticides that are currently under regulatory review.

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Subject: RE: New Tier 2 Incident: flumethrin, imidacloprid

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Best,
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To: OPP Incidents Screening <Opp_Incidents_Screening@epa.gov>; Fletcher, Rachel <fletcher.rachel@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>
Subject: RE: New Tier 2 Incident: flumethrin, imidacloprid

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To: Fletcher, Rachel <fletcher.rachel@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>
Subject: New Tier 2 Incident: flumethrin, imidacloprid

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Have a good day,

Heather McFarley
Secretary, Incident Screening Team

Message

From: Rivera-Lupianez, Ana [Rivera-Lupianez.Ana@epa.gov]
Sent: 5/18/2018 4:38:56 PM
To: Britton, Cathryn [Britton.Cathryn@epa.gov]; Snyderman, Steven [Snyderman.Steven@epa.gov]
CC: Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Dutch, Veronica [Dutch.Veronica@epa.gov]; Miller, Robert [Miller.Robert@epa.gov]
Subject: RE: NPIC pet incidents
Attachments: 2448_2018.pdf; 2017-10266.pdf; 2017-8944.pdf; 2017-7733.pdf; 2016-7313.pdf; 2015-9150.pdf

Hi Cathryn,

Attached are some reports that I found on my files. I believe these were submitted to us as "special interest reports" (phone call and email inquiries to NPIC) and not through the vet portal. As I mentioned, we will ask NPIC for a compilation of all Seresto incidents received.

Thanks,
Ana

From: Rivera-Lupianez, Ana
Sent: Friday, May 18, 2018 12:14 PM
To: Britton, Cathryn <Britton.Cathryn@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>
Cc: Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Dutch, Veronica <Dutch.Veronica@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>
Subject: RE: NPIC pet incidents

Hi Cathryn,

I only sent you the last two reports as an example, but NPIC have provided individual reports for the last two years
Ex. 5 Deliberative Process (DP) We can submit a data request for all incidents involving Seresto collar (ais imidacloprid and flumethrin) that have been reported to NPIC since the products were first registered. Can you provide a date range?

Thanks,
Ana

Ana Rivera-Lupiañez
Pesticide Worker Safety Programs
Office of Pesticide Programs
Environmental Protection Agency
rivera-lupianez.ana@epa.gov
(703) 308-6841

From: Britton, Cathryn
Sent: Friday, May 18, 2018 12:02 PM
To: Rivera-Lupianez, Ana <Rivera-Lupianez.Ana@epa.gov>; Snyderman, Steven <Snyderman.Steven@epa.gov>
Cc: Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Dutch, Veronica <Dutch.Veronica@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>
Subject: RE: NPIC pet incidents

Thanks everyone for all the background.

Ana – just to clarify, I didn't see anything specific about Seresto in the FY16 or FY17 reports, is that correct?

I think we'd be interested in any/all of the reports related to Seresto that have been submitted through the vet portal.

Ana/Steven – if you two can coordinate how we can get some of this information from NPIC I'd appreciate it.

Thanks again,
Cathryn

From: Rivera-Lupianez, Ana
Sent: Friday, May 18, 2018 9:51 AM
To: Snyderman, Steven <Snyderman.Steven@epa.gov>
Cc: Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Dutch, Veronica <Dutch.Veronica@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>
Subject: RE: NPIC pet incidents

Thanks for the head's up, I was not aware and I'll add Marianne to the group.

Thanks,
Ana

From: Snyderman, Steven
Sent: Friday, May 18, 2018 9:37 AM
To: Rivera-Lupianez, Ana <Rivera-Lupianez.Ana@epa.gov>
Cc: Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Dutch, Veronica <Dutch.Veronica@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>
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That's really helpful to know. I actually just heard back from IST as well and they provided me a helpful prioritization memo with when they utilize NPIC data [attached]. Just a note, I believe Marianne Mannix is the point of contact now as Nathan Sell is no longer with the Agency.

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From: Rivera-Lupianez, Ana
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I'm including Bob Miller to the email chain since he receives the incidents submitted via the Vet portal. We will coordinate a conference call with NPIC at your convenience.

Please let me know if you have any questions.

Thanks,
Ana

Ana Rivera-Lupiáñez
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Office of Pesticide Programs
Environmental Protection Agency
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Thank you again.

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<Dutch.Veronica@epa.gov>

Subject: RE: NPIC pet incidents

Hi Cathryn,

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Veterinarians and qualified medical professionals submit pesticide-related illness reports using NPIC's "Veterinary Incident Reporting Portal (VIRP)" web reporting system. The data collected via NPIC's Vet portal (vet report) is submitted to EPA on quarterly and annual reports (copies of 2016 and 2017 reports are attached).

NPIC also can prepare customized data reports. I'll be happy to coordinate a meeting with the grantee to discuss your specific needs.

Thanks,

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Sent: Thursday, May 17, 2018 4:24 PM

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Cc: Snyderman, Steven <Snyderman.Steven@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Dutch, Veronica <Dutch.Veronica@epa.gov>

Subject: NPIC pet incidents

Hi Ana,

I have a question/request for you. We have been receiving some recent updates regarding pet incidents and the seresto (flumethrin/imidacloprid) collar from the incident team.

A question was asked by Rick about the current pet incidents coming into NPIC from the vet community.

We were asked to reach out to you to help figure out what information NPIC might have to help us.

I'm copying Steven Snyderman – who is helping to coordinate this effort in PRD. I'm not sure if you know Steven, but if you have any information to share with us, please let him know.

I'm also copying Melanie and Veronica – because they are also working on flumethrin.

Thanks,

Cathryn



2018 REFERRAL TO EPA

LOG: 2448

Date: 4/25/18

City, State: Lewisburg, WV

Narrative: Voice mail message. Returned call at 09:01 on 04/25/2018. Caller (veterinarian) wishing to report a possible adverse reaction to a Seresto collar (EPA registration number 11556-155 (active ingredients imidacloprid, flumethrin)). Caller reported that a client bought two Seresto collars from their office on 4/6/2018, and applied them to his dogs after returning home. Caller reported that within 24 hours, one of the dogs (9 year old, 63 lb neutered male Australian Shepherd mix) was brought to the emergency clinic. Caller reported that the dog cried out during the night, vomited several times, had uncontrolled urination, was ataxic, and couldn't walk. Caller reported they tested the dog for antifreeze (which was negative), did an examination, found that he had very high white blood cell count, and gave him sub-cutaneous fluids and a couple injections of medication. Caller reported that the dog recovered within 24 hours and was sent home.

Caller reported that the owner did not think that the collar was related to the dog's condition, and reapplied the collar on 4/22/2018. Within 48 hours the dog had a similar episode, with symptoms including crying out, vomiting, and possible seizures. Caller reported when he was brought to the clinic early afternoon on 4/24/2018 he was found to have "blunted mentation, knuckling, and wobbly on his rear legs". Caller reported he was tested and found to have an even higher white blood cell count, was given subcutaneous fluids and injections again, a catheter, and they tried to refer him to an emergency clinic. Caller reported that the dog passed away within two hours of presentation at the clinic. Caller reported there were no dermal symptoms observed, and they have already reported both reactions to the manufacturer (Bayer). Discussed NPIC services, including reporting process for incidents. Entered information into NPIC VIRP case # NPIC4251120. Offered to email additional information about NPIC's veterinary reporting portal, and caller provided email address. Sent requested email. Email response:

Thank you for contacting the National Pesticide Information Center (NPIC) today. As we discussed over the phone, I'm providing additional resources regarding our online Veterinary Pesticide Incident Reporting Portal. The portal was created so that veterinarians and their staff could report adverse reactions to pesticides observed in animals. This includes reactions to flea & tick products, along with any other pesticide. I have entered today's incident on your behalf; in the future you may either enter incidents directly or call and report them verbally.

Introduction to the Veterinary Pesticide Incident Reporting Portal
<http://npic.orst.edu/factsheets/VIRP.html>

Veterinary Pesticide Incident Reporting Portal
<http://npic.orst.edu/vet/>

We hope your office will consider reporting future adverse reactions to pesticides you observe



2018 REFERRAL TO EPA

LOG: 2448

in your patients. If you have any additional questions, or you need help with any of the resources provided, please contact us at 800-858-7378, Monday - Friday from 8:00 am to 12:00 pm PT.

Caller phoned back in to provide EPA Registration Number, see log 2470. Resources used: "Registration Decision for the New Active Ingredient Flumethrin for Use in Cat and Dog Collars", & NPIC Fact Sheet.



2017 REFERRAL TO EPA

LOG: 10266

Date: December 6, 2017

City, State: Avonmore, PA

Narrative: Caller seeking to report an incident involving EPA registration number 11556-155 (active ingredients imidacloprid, cyano (4-fluoro 3-phenoxyphenyl)methyl 3-[2-chloro-2-(4-chlorophenyl)ethenyl]-2,2-dimethylcyclopropanecarboxylate] [NPIRS]). Caller reported his dog (3 years, unknown weight, fixed male, German shepherd) died after use of a Seresto Flea Collar on 11/29/17, one week before the NPIC call. Caller said the collar was put on the dog on 11/12/17 and that about 3-4 days later, the dog had a seizure with the collar still on. Caller reported he took the collar off the dog and then about a week-and-a-half later, he and the dog were out in the woods on his farm, the dog ran up to him and then fell over dead. Caller reported he already talked to the manufacturer, who he said asked for the product's lot number and told him it was impossible for the collar to have affected his dog in that way. Caller reported he also talked to his vet afterward and that his vet told him there were no blood or other tests to show the product in the dog's system. Caller said he also already talked to EPA. Caller further reported that he's used the same collars on other animals before with no issues and so wondered if it was a bad lot, but then got to researching and found concerns with the collars going back to 2014. Caller reported that he has alpacas, horses, cats and dogs on his home farm.

Discussed NPIC services, including that NPIC does not have regulatory authority, but that the State Lead Pesticide Agency was the entity in his area responsible for regulation of pesticide use, including having an office for incident reporting; provided state lead contact. Discussed the Consumer Product Safety Commission as another resource for complaints relating to products sold in the U.S.; provided contact. Discussed how NPIC collects data that is accessible for review by the EPA, including in relation to the reregulation review process.

Resources used:

Hazardous Substances Data Bank (HSDB)

California EPA "Summary of toxicology data, flumethrin"

Date: October 2, 2017

City, State: St. Louis, MO

Narrative: Caller Ex. 5 Personal Privacy (PP) seeking information on how long her reaction to a Seresto Flea Collar (active ingredients flumethrin, imidacloprid) may last, and wants to report her reaction. Caller reported that she applied a collar to her two cats and small dog 9 days ago, and by the next evening her lips and tongue were swollen, her eyes were beginning to swell, she had tingling and burning inside her mouth and on her lips, and she had blisters form inside her mouth. Caller reported she picks up and carries her dog frequently throughout the day, and each time she picks it up she kisses it on the head. Caller reported that it took several days before she realized that the collar was the only thing that had changed in the house, and she removed the collars four days after she had put them on.

Caller reported she called the manufacturer (Bayer Healthcare) on the day she removed the collars, was told that in rare cases people do have these reactions, was advised to use vitamin E on her skin, and to shampoo the animals. Caller reported she washed all of the animals that day. Caller reported that the next day (four days ago) she went to the urgent care, was given a steroid shot and a 5-day supply of steroids, and was told to not use the vitamin E oil. Caller reported that the swelling has gone down, but the tingling and burning on her lips and mouth are still present, and it has influenced her ability to eat and has a hard time eating anything with salt because it burns. Caller reported there were no symptoms for any of her animals from the collars. Caller reported she has since returned the collars and their packaging back to the store where she bought them.

Discussed NPIC services, including the inability to provide medical treatment advice. Discussed risk equation concepts, including toxicity and routes of exposure. Discussed the toxicity of the active ingredients, and reported symptoms from exposure to them (NPIC Fact Sheet, "Inchem UKPID Monograph Flumethrin", & "NY DEQ Human Health Assessment Flumethrin - 2012"). Discussed providing the Recognition and Management of Pesticide Poisonings to her medical provider as a resource for toxicology information on active ingredients, and provided NPIC website.



2017 REFERRAL TO EPA

LOG: 7733

Date: August 23, 2017

City, State: Hadley, NY

Narrative: Caller, Ex. 6 Personal Privacy (PP), seeking to report an adverse reaction to a Seresto flea collar (active ingredients flumethrin, imidacloprid, per Bayer.com). Caller reported there was a dog staying with him and his wife beginning three weeks ago. Caller reported when the dog first arrived he had normal contact with the dog and did not have any symptoms. Caller reported the dog got into his bed and the following night he broke out in hives and was itching uncontrollably. Caller reported he went to the ER and was treated with prednisone. Caller reported he went home and was there for 24-48 hours and had the same reaction and went to the ER a second time. Caller reported after the collar was removed from the dog he had no further symptoms. Caller reported he had contacted Bayer but they told him he would have to wait 24 hours to speak to someone. Caller reported he wanted to ensure the incident was reported and asked who else he could contact. Discussed NPIC services, including being a reporting body to the EPA. Discussed the role of the EPA and State Lead Pesticide Agencies in regulation of pesticide products. Provided contact information for the State Lead Pesticide Agency to discuss the caller's concerns.

Date: August 1, 2016

City, State: Johnson City, NY

Narrative: Caller wishing to report a reaction her dog (100 lb, 8 year old, intact male German shepherd) had to a dog collar, EPA registration number 11556-155 (active ingredients imidacloprid, flumethrin). Caller reported that she applied the collar to the dog on 06/29/2016, that he lives in an outdoor kennel, and that she noticed the next morning that the dog was shaking his head more than normal, but her husband had an accident that kept her from paying much attention to the dog for quite awhile. Caller reported that on 07/12/2016 she was visiting the dog in his outside kennel, touched his head and ears and noticed that they were very hot and felt like they were "on fire". Caller reported that she called her veterinarian, and was told to check the dog's neck to see if he had sores, and if he did to remove the collar and bathe him. Caller reported that the dog did have noticeable oozing sores on his neck, she washed him with Dawn dish soap, and the veterinarian prescribed antibiotics and steroids to help with the inflammation without a clinic visit.

Caller reported that she took the dog into the veterinarian on 07/19/2016 because his symptoms seemed to continue, and the vet shaved the dog around his neck and down to his shoulder blades because the sores covered that entire area. Caller reported that the dog had an ear infection also, and was prescribed another antibiotic, and another cream ointment. Caller reported that she has been using a medicated shampoo on the dog, and has had to move him indoors while he has open wounds on his skin. Caller reported that she that she has been incredibly disappointed with the response of the manufacturer (Bayer Healthcare) to her situation. Caller reported she is planning on doing everything she can to try to stop other consumers from going through a similar experience.

Discussed NPIC services. Discussed the registration of products through both federal and state agencies, and provided contact information for the State Lead Pesticide Agency as a resource for reporting concerning pesticides. Resources used: Registration Decision for Flumethrin for Use in Cat and Dog Collars - 2012, NPIC Fact Sheet, & Hazardous Substances Data Bank (HSDB).



2015 REFERRAL TO EPA

LOG: 9150

Date: 9/22/2015

City, State: Unknown – Inquiry received via email

Narrative:

Email received:

I saw in a post this was the place to address this issue but I am not sure.

This is regarding Seresto's flea and tick collar. My dog has had this collar for about 6 months now wearing it constantly. Ever since around the time she started wearing it she started getting sick and having seizures. Her mouth would turn white and she would just be out of it. We spent \$3000 to find out what's wrong with blood test and overnight stays and they said all of her blood work was fine but she could be having seizures. It came over me to look up the Seresto Collar for some reason and find out more information. To my surprise there is MORE information regarding this product and seizures in dogs on the internet. We have taken my dog off of this and she is doing fine now, no problems anymore. This product needs to be off the market immediately and reevaluated. I am beyond angry this has happened but happy I found out what it is. This product was recommended by my vet who I thought I could trust. I am disgusted that this has been let on the market.

Email response:

Thank you for emailing and reporting an adverse health effect to a pesticide. I am very sorry to hear about your situation. I am glad to hear your dog is no longer experiencing problems, but if additional symptoms arise, you may consider contacting your pet's regular veterinarian or one of the animal poison control centers listed below.

ASPCA Animal Poison Control Center at 1-888-426-4435 (\$65.00 credit card fee)
Pet Poison Helpline at 1-800-213-6680 (\$49.00 credit card fee)

Please call us at 800-858-7378 Monday - Friday from 8:00 am - 12:00 pm Pacific Time and speak directly to a Pesticide Specialist to further report and discuss the situation. In order to complete your report, we need to identify the specific product. Please have the EPA registration number or the active ingredient(s) available when you call. This information is specific to each product and located on the label. If you no longer have the package, you might consider visiting or contacting the retail store from which it was purchased to obtain this information.

The National Pesticide Information Center at Oregon State University is an information service and has no regulatory authority in relation to pesticides. However, our incident reports are made available to the U.S. EPA. Furthermore, our website features a reporting database that veterinarians can use to report adverse effects related to pesticide products. Please be aware this resource is only for veterinarians. Please consider encouraging your veterinarian to submit



2015 REFERRAL TO EPA

LOG: 9150

a report through this portal when they observe adverse reactions to pesticide products. The link for this portal is provided below.

Veterinary Pesticide Adverse Effects Reporting

<http://npic.orst.edu/vet>

An additional mode of reporting adverse effects is by contacting the manufacturer. Under FIFRA 6(a)(2), manufacturers are required to submit adverse effects information about their products to the U.S. EPA. Manufacturer contact information can be accessed from the following link:

<http://npic.orst.edu/ingred/manuf.htm>

Again, please contact us at 800-858-7378, Monday - Friday from 8:00am to 12:00pm Pacific Time. We look forward to answering any questions you have, and we will document your situation further.

Message

From: Snyderman, Steven [Snyderman.Steven@epa.gov]
Sent: 5/18/2018 1:37:29 PM
To: Rivera-Lupianez, Ana [Rivera-Lupianez.Ana@epa.gov]
CC: Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Dutch, Veronica [Dutch.Veronica@epa.gov]; Britton, Cathryn [Britton.Cathryn@epa.gov]; Miller, Robert [Miller.Robert@epa.gov]
Subject: RE: NPIC pet incidents
Attachments: High-Priority Incident Screening Process 2.2.18.docx

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I'm also copying Melanie and Veronica – because they are also working on flumethrin.

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Message

From: Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]
Sent: 3/3/2021 2:41:41 PM
To: Miller, Robert [Miller.Robert@epa.gov]
Subject: RE: Flumethrin Question

Hi Bob,

Thanks for the email. We've received notice of the article published yesterday and are working to address it.

Thanks,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Miller, Robert <Miller.Robert@epa.gov>
Sent: Wednesday, March 03, 2021 9:40 AM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: FW: Flumethrin Question

Hi Jackie,

Below is new article on Seresto.

Take care,

Bob

From: Rudd, Jaime@Wildlife <Jaime.Rudd@wildlife.ca.gov>
Sent: Tuesday, March 02, 2021 4:19 PM
To: Miller, Robert <Miller.Robert@epa.gov>
Cc: Palmer-Townsend, Marilyn@CDPR <Marilyn.Palmer-Townsend@cdpr.ca.gov>
Subject: Flumethrin Question

Hi Robert –

I was just this article about flumethrin and was wondering if you had any additional info or who the proper contact would be, <https://www.usatoday.com/story/news/investigations/2021/03/02/seresto-dog-cat-collars-found-harm-pets-humans-epa-records-show/4574753001/>.

We have been using Seresto collars on endangered San Joaquin kit foxes for the last 5 years (I actually did my dissertation on their safety and efficacy in preventing sarcoptic mange). This is a little concerning but I am not sure if there is a lot of merit to the reports or not and how I could find out what was reported. In the cases of domestic dogs mortalities, it seems mortality occurred 2-3 months after the collar was put on. We have not had any problems in kit foxes but it is a little concerning.